Subject ID: 01-029
Site ID: 01

A. Demographics

1. Date of Screening Visit	29/Jan/2021 *DD/MMM/YYYY*
2. Date Informed Consent Obtained	29/Jan/2021 *DD/MMM/YYYY*
3. Was Informed Consent explained and personally signed by the Subject?	(•) Yes ( ) No
4. Was a copy of the Informed Consent provided to the Subject?	(•) Yes ( ) No
5. Was a copy of the signed Informed Consent provided to the Subject?	(•) Yes ( ) No
6. Was consent completed in advance of any study procedures/assessments?	(•) Yes ( ) No
7. Approved ICF Version Date	01/Apr/2019 *DD/MMM/YYYY*
8. Protocol Version # and Date:	D 01/Apr/2019 *DD/MMM/YYYY*
9. Date of Birth	12/Nov/1936 *DD/MMM/YYYY*
10. Age at enrollment	84
11. Gender	( ) Male (•) Female
12. Race and Ethnicity	( ) Caucasian/White ( ) African/Black (•) Hispanic/Latino ( ) Pacific Islander ( ) Asian ( ) Other ( ) Not disclosed

Endovascular Treatment of Communicating Hydrocephalus with the eShunt System
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PATIENT INFORMATION/INFORMED CONSENT

Endovascular Treatment of Communicating Hydrocephalus with the eShunt System

A Pilot Study to Evaluate the Safety and Effectiveness of the CereVasc eShunt™ System in the Treatment of Communicating Hydrocephalus

PRINCIPAL INVESTIGATOR: **Pedro Lylyk, M.D.**

INSTITUTION: **La Sagrada Familia Clinic**
Jose Hernandez 1642
CABA, Argentina C1426B

SPONSOR: **CereVasc, LLC**
2120 Commonwealth Avenue Unit 1
Auburndale, MA 02466

LEGAL REPRESENTATIVE IN ARGENTINA: **Técnicas Mínimo Invasivas S.A.**
Eduardo Sessa
Av. Rivadavia 4390, 10 piso Oficina A
Ciudad Autónoma de Buenos Aires (C1205AAQ)
Teléfono (+54) 911 4411-4811

ARGENTINE REGULATIONS REQUIRE WRITTEN INFORMED CONSENT FROM PARTICIPANTS PRIOR TO PARTICIPATION IN A RESEARCH EVALUATION SO THAT THEY KNOW THE NATURE AND RISKS OF PARTICIPATION AND CAN DECIDE TO PARTICIPATE OR NOT TO PARTICIPATE IN A FREE AND INFORMED MANNER. YOU ARE ASKED TO READ THE FOLLOWING MATERIAL TO ENSURE THAT YOU ARE INFORMED OF THE NATURE OF THIS RESEARCH EVALUATION AND OF HOW YOU WILL PARTICIPATE IN IT IF YOU CONSENT TO DO SO. SIGNING THIS FORM WILL INDICATE THAT YOU HAVE BEEN SO INFORMED AND THAT YOU GIVE YOUR CONSENT.

You are being asked to participate in a study that involves collecting data on the clinical results of the eShunt™ System for the treatment of your communicating hydrocephalus.

IMPORTANT: You should sign the Patient Informed Consent Form only after you have read and understood the following, as well as receiving verbal information and had any questions answered. Regulations require written informed consent from patients prior to participation in a research study. You should feel that signing this form is something you are doing voluntarily. If you feel that you are under pressure, we advise you to postpone your decision. If you decide to participate, you are free to withdraw your consent at any time. You are asked to read the following material to ensure that you are informed of the nature of this research study and how you will participate in it if you consent to do so. Signing this form will indicate that you have

been so informed and that you give your consent. Regardless of what you decide, you will continue to receive the best treatment for your condition at all times.

PURPOSE OF STUDY

You have been diagnosed with communicating hydrocephalus, a condition characterized by persistent elevated pressure in your brain, due to the cerebrospinal fluid (CSF, the fluid that surrounds your brain), is not being adequately drained. This is often due to bleeding in your brain. Your doctor would like to treat your condition using the eShunt System. The eShunt System is a minimally invasive method (not requiring an open surgery, access the implant site through the vessels) of treating communicating hydrocephalus. The eShunt System includes a novel eShunt Delivery System and eShunt Implant, a permanent implant deployed in a minimally invasive, procedure. The eShunt Implant is designed to drain excess cerebrospinal fluid from the intracranial subarachnoid space (SAS, area of your brain with channels containing CSF) into a vein so it can be removed by the body. It will be used at the same time as another device that will also drain the fluid from your brain.

The study has been reviewed by the regulatory authorities or by the Ethics Committee. This is the first time that this system will be used in human clinical evaluation. There are commercially approved devices for the treatment of your condition and the eShunt System is considered experimental for treating your communicating hydrocephalus. However, it is possible that the eShunt System could help resolve your symptoms. Your participation in this study will help us evaluate its usefulness to treat your condition.

This evaluation will be completed at a single center and will enroll up to 30 subjects.

STUDY REQUIREMENTS AND PROCEDURES

There are certain requirements that need to be met for you participate in this study. The study Doctor will review these with you after you sign this informed consent form. Once your doctor has determined that you meet all of the requirements for participation in the study, you will receive the eShunt System procedure. The eShunt System is an experimental minimally invasive procedure that potentially provides an improvement over the current standard of care procedure (a surgical procedure where an opening is made in your skull and a catheter is passed through a portion of the brain and then passed under the skin to your abdomen). The eShunt System procedure will begin with a series of radiological studies that will include a Computerized Tomography Scan (CT, a procedure where x-rays are used to create cross-sectional images) and Magnetic Resonance Imaging (MRI, a procedure where a large magnet is used to create images) of your head. These studies will be used by your Doctor to ensure you are a candidate for the eShunt System procedure and to ensure proper placement of the eShunt Implant. Following these studies, you will be transported to the angiography suite of the clinic to complete the eShunt System procedure. You will receive anesthesia at that time for your comfort as well as a broad spectrum antibiotic to minimize the risk of post-operative infection. During the procedure your doctor will thread a very small catheter, inserted into a vein in your groin area, up to an area at the base of your brain and will place the eShunt Implant at that time. The eShunt Implant will allow the excess fluid that is causing your communicating hydrocephalus to flow from your brain into a small vein, which will relieve the excess fluid and pressure in your head.

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Following placement of the eShunt Implant, you will be moved to a recovery area to awaken from your anesthesia and will then be returned to the intensive care unit for continued monitoring. During the next 48 hours following the procedure, the pressure in your head will be monitored and the external drain that was previously placed will be closed. Once the eShunt Implant is verified as working properly, the external drain will then be removed. If the pressure in your head is not reduced to an acceptable level with the eShunt Implant, you will have a procedure to place the standard of care drainage catheter (VP drainage). The eShunt Implant may then be left in place or removed based on the Investigator's assessment of your condition and need. If the eShunt is removed, your doctor will thread a very small catheter, inserted into a vein in your groin area, up to an area at the base of your brain and will remove the eShunt Implant at that time. After placement of the alternative shunt you will be removed from the study. If the Investigator decides to not remove the eShunt, you will remain in the study and complete the required follow up visits. In both situations, your condition will continue to be monitored by the Investigator and you will be discharged from the clinic at the earliest time possible, as determined by your doctor.

Your participation in this study will require a total of 10 visits. The visits are: Screening, eShunt System procedure, 48 hours after the procedure, 7, 30, 60, 90 and 180 days and 12 and 24 months after the procedure. Each of these visits is an important part of the study and will include the requirements detailed in the schedule below.

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Assessment	Screening	Implant Procedure	Within 48 hours	7 Days ± 2 days	30 Days ± 7 days	60 Days ± 14 days	90 Days ± 14 days	180 Days ± 14 days	12 Mo. +/14 days	24 Mo. +/- 21 days
Informed Consent	X									
Pregnancy Test (before CT/MRI scan)	X	X	X		X		X	X	X	
Hunt and Hess	X		X	X	X	X	X	X	X	X
Targeted history and physical with neurological exam	X		X	X	X	X	X	X	X	X
Serum Labs • Chem 20 • CBS with Diff • PT &/or PTT	X			X	X	X	X	X		
EVD Clamp Test	X		X							
ICP measurement	X		X							
MRI with Gadolinium	X						X			
MRI (Axial T2-weighted)			X					X		
CT (1 mm slice)	X				X				X	
3D rotational angiography or DynaCT/XperCT with 3D road-mapping & live fluoroscopy		X								
Cardiac Echocardiogram	X									
Adverse Events		X	X	X	X	X	X	X	X	X
Medications	X	X	X	X	X	X	X	X	X	X

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The following is a description of each assessment that will be included in this study:

Pregnancy Test: If you are female of child bearing potential, a pregnancy test will be completed in advance of the procedure and before each CT and MRI evaluation. If you become pregnant during the study, you will not complete the CT scans or MRI scan with contrast. You will also be followed through completion of your pregnancy.

Hunt and Hess Assessment: A standard assessment of your condition will be completed using a well-known validated scale.

Targeted History and Physical with Neurological Exam: Your past medical history will be collected, and a brief physical exam will be conducted to document any changes during the course of the study. In addition, the physical exam will include a standard neurological evaluation where improvements in your function related to your condition are assessed.

Serum Labs: Blood will be taken from your arm with a needle to test for proper clotting and other standard testing of your blood serum chemistry.

EVD Clamp Test: The standard of care is to place a drain in your skull, attached to a catheter, to relieve excess pressure. During this test the drain is temporarily closed (clamped) to determine if the pressure in your brain becomes elevated. If it becomes elevated, you are a candidate for the eShunt System procedure.

ICP Measurement: This is a test where the pressure in your brain is measured, through the drain you already have in place.

MRI: An image evaluation using a contrast dye material (gadolinium) to better show your brain that looks at your skull, brain and nearby anatomy. This information will be used by your study Doctor to verify if you are a candidate for the eShunt System procedure, assist in placing the eShunt Implant and to evaluate your improvement during the follow-up period. Also, an MRI without dye will be completed within 48 hours after the eShunt System procedure and again at the 180 day follow up visit.

CT: A radiological evaluation to help ensure your skull and anatomy are acceptable for placement of the eShunt Implant by looking at your skull, brain and nearby anatomy. This information will be used by your study Doctor to verify you are a candidate for the eShunt System procedure. It will be repeated at the 30 day and 12 month follow up visit.

Echocardiogram: A non-invasive evaluation that uses sound waves to create a picture of your heart to ensure there are no defects that would preclude you from participating in this study.

3D Rotational Angiography or DynaCT/XperCT with 3D Road-mapping & Live Fluoroscopy: This radiological procedure is a way for the study Doctor to see the eShunt System during the procedure to ensure that everything is placed in the right location.

eSHUNT SYSTEM PROCEDURE RISKS

Potential risks associated with the eShunt System procedure include:

- Damage to a blood vessel from delivery componentry

- Bleeding into your brain
- Clot or air bubble in your blood vessels from the device
- Blockage of your blood vessel from a clot
- Tear in the membrane surrounding your brain
- Infection
- Hole or tear in a blood vessel
- Nerve damage
- Worsening of your condition

eSHUNT IMPLANT RISKS

The procedure risks listed above may also be risks related to the eShunt Implant. Procedure-related risks are those that occur as a consequence of the eShunt Implant placement; whereas, device-related risks are those that occur as a consequence of eShunt Implant malfunction. In addition to the risks listed above, the eShunt System may have unique risks associated with its permanent implant. These risks include:

- Allergic reaction to the device materials
- Parts of the device wearing out
- Device components break, separate or result in formation of a blood clot requiring removal and replacement
- Device becoming blocked and requiring removal and replacement
- Formation of a blood clot that blocks a blood vessel or organ

All these potential risks are treatable, and if treated timely, your life should not be at risk. Your doctor will discuss with you all the signs and symptoms so that you pay attention to them. If you experience any of the signs and symptoms discussed with your doctor, call him immediately and he will tell you if you should go to a hospital for any treatment.

There may be other device-related problems that are not known yet. If during the trial new information becomes available about other problems, every effort will be made to inform you immediately.

OTHER STUDY RISKS

There are additional risks associated with anaesthesia, MRI and CT scans.

Anaesthesia risks include postoperative confusion, heart attack, pneumonia and stroke, especially in older adults and individuals undergoing lengthy procedures.

Risks associated with MRI include potential increase body heat, risk of injury from metal objects brought inside the scanner (implants, pacemakers) and allergic reaction to or retention of gadolinium dye.

Risks associated with the CT scan include a very small chance of cancer due to the radiation.

RISKS TO PREGNANCY

The risks of using the eShunt Implant on a pregnant woman are unknown. Pregnant women may not take part in this research trial.

Child bearing age women could only be considered as potential candidates if they are not planning to become pregnant during the length of this study.

Tests will be carried out to rule out pregnancy during the study screening to see if you are a candidate for the study and immediately before the placement of the eShunt. If you become pregnant before the eShunt procedure, you will not be able to participate in the study.

In addition, at each follow-up visit that includes a CT scan or MRI, or if a possible pregnancy is reported, a urine blood test will be performed to ensure there is no exposure to radiation and you will be given the test results.

If you become pregnant during the study, you should notify Dr. Lylyk immediately. Dr. Lylyk will advise you on the best option for you to follow to ensure your safety and welfare.

ANTICIPATED POTENTIAL BENEFITS

Based on the performance of other CSF drains that have successfully relieved symptoms of communicating hydrocephalus, there is reason to believe that the eShunt System could also relieve your symptoms. However, there is no guarantee of this and your symptoms could remain unchanged. There will be no other direct benefit to you because of your participation in this study beyond the potential benefit of the eShunt System treatment and associated visits to your physician. However, data collected in this study may help doctors to provide better treatment for communicating hydrocephalus in the future.

ALTERNATIVE TREATMENTS

Your participation in the study is optional.

If you decide not to participate in this study, this will not affect your future care. Your doctor will treat you with the standard of care for your condition, that consists in the derivation of the cerebrospinal fluid by means of a surgical procedure in which a catheter is placed from a portion of the brain to your abdomen.

CONFIDENTIALITY

The information collected in this trial shall be disclosed to the Sponsor and the Ethics Committee. Said information may also be disclosed to regulatory authorities that make decisions to approve the device.

The results of the trial may be disclosed to contribute to future scientific research and for general scientific purposes subject to the applicable laws and regulations.

The information collected in this trial (which will not have any data that can identify you) may be reported to other countries to be processed for the purposes previously described within this form.

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Your information will be treated confidentially, and, to the extent permitted by the applicable laws and regulations, your personal information will not be publicly disclosed. The findings in this trial may be presented at scientific meetings. Nevertheless, your identity will be protected in these events.

The National Directorate for the Protection of Personal Data, under the Agency of Access to Public Information, the body responsible for controlling the law 25.326, has the power to attend to inquiries, complaints or claims that are filed in relation to any question regarding the Protection of personal data. For this purpose, you can contact: Avenida Presidente General Julio Argentino Roca 710 - CABA 2nd Floor, www.argentina.gob.ar/aaip

COSTS OF TREATMENT AND STUDY PARTICIPATION

CereVasc, LLC will cover the expenses associated with the use of the eShunt System. The eShunt System will be free of charge. The trial sponsor will pay for the tests that may be required for your taking part in this trial. You will not be charged for the device itself or for anything related with the study.

PAYMENT FOR STUDY PARTICIPATION

CereVasc, LLC is compensating the institution where the trial is being conducted. No participant will be paid for taking part in this trial. If needed, upon completion of the follow-up visits, each participant will receive monetary reimbursement (through the trial doctor) for food or transportation expenses incurred.

TREATMENT OF RESEARCH RELATED INJURY

Please contact your study doctor for medical treatment if you believe you are injured or become ill as a result of this study. The trial doctor will provide you medical care immediately when you need it, and he will also treat you for any complication that may occur during the trial because of your participation in the trial.

If during the course of the study you suffer any physical damage, injury or any complication in your health related to the medical product under investigation or the procedures related thereto; CereVasc, LLC, represented in Argentina by TECNICAS MINIMO INVASIVAS SA will provide you all the necessary and immediate medical attention for treatment. The sponsor shall provide the costs of such assistance. Also, CereVasc, LLC represented by TECNICAS MINIMO INVASIVAS SA is responsible for the damage suffered to your health as a result of your participation in the study. It is reported that CereVasc, LLC represented by TECNICAS MINIMO INVASIVAS SA (TMI SA) has contracted an insurance provided by Chubb, coverage certificate Number C0008198.

The sponsor has not agreed to make any payments directly to you. The sponsor has not agreed to pay for injuries or illnesses that are the result of a pre-existing condition.

CONTACT FOR RESEARCH QUESTIONS OR EMERGENCY

If you have any questions about the research or develop a research-related problem or injury, you should contact Dr. Lylyk's office is located at Jose Hernandez 1642, CABA and you can call +54 11 4787-2220 or +54 11 6343-7888 after business hours, weekends or holidays.

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This study has been reviewed by the Independent Ethics Committee Clinica La Sagrada Familia and by National Independent ethic committee (CEIC) a panel of independent people. The purpose of this group is to protect the rights and safety of patients who voluntarily participate in research studies. If you have questions about your rights as a participant, questions or concerns about your privacy or you have a complaint or questions about the participation in the study, you can contact:

La Sagrada Familia Hospital
Sito en José Hernández 1642, TEL. + 54 (11) 4706-3953
Presidente: Dr. Carlos Ingino

National Clinical Investigations (CEIC)
Sito en Larrea 1381, 3ro A, C1027 AAP, Tel. +54 11 4826 3962
Presidente: Dr. Diego Hernán Fridman
info@comitedeeticaceic.com.ar

This study has been submitted for ANMAT approval. If you have any questions regarding the treatment or procedures of this clinical research, you can consult ANMAT responds to 0800-333-1234 (toll free) or 011-4340-0800 Monday through Friday from 8 AM to 5 PM.

You should not sign this form unless you have had the opportunity to clarify all your doubts and has obtained satisfactory answers to all your questions.

VOLUNTARY PARTICIPATION/WITHDRAWAL AND TERMINATION

Taking part in this trial is voluntary. You may choose not to take part or may leave the trial at any time without any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the trial before its completion, you will be asked to see the doctor for a last office visit.

The trial doctor may at any time take you out of the trial if he decides that is best for your well-being, if you fail to follow the trial guidelines, or if serious adverse events are discovered. Further, the Ethics Committee and/or Sponsor may stop your participation in this trial at any time, with or without your consent. If you stop participating in the trial, your doctor will provide you with an adequate alternative treatment.

Dr. Lylyk may withdraw you from the trial, with or without your consent, due to any of the following reasons: a) based upon criteria for your medical care improvement, b) if you fail to follow the trial guidelines, c) if serious adverse events are discovered.

DATA PROTECTION

Within the provisions of the national data protection law, Law No. 25,326, the study center and the sponsor will have the joint responsibility to act as "custodians" of the data in order to ensure that their information is protected. The law gives you the right to see, consult and copy all the information obtained about you and, if necessary, to request corrections, both during the performance of the trial and after it has ended. The law confers on you the right to access your clinical record in relation to the trial free of charge at intervals of not less than six months, unless

a legitimate cause is identified, as established in Art. 14 Inc. 3 of Law 25,326 (Data Protection Law)

BY SIGNING THIS FORM YOU ARE ACCEPTING TO PARTICIPATE IN A MEDICAL RESEARCH IN CLINICAL PHARMACOLOGY OR IN MEDICAL TECHNOLOGY OF EXPERIMENTAL CHARACTER AUTHORIZED BY THE NATIONAL ADMINISTRATION OF MEDICINES, FOOD AND MEDICAL TECHNOLOGY (ANMAT). IF YOU HAVE ANY DOUBT ABOUT WHAT HAVE BEEN EXPLAINED BY YOUR DOCTOR OR THE ETHICS COMMITTEE, BEFORE SIGNING YOU KNOW THAT YOU CAN CONSULT "ANMAT RESPONDE", FREE LINE 0800 333 1234 OR 011 4340 0800 FROM MONDAY TO FRIDAY FROM 8:00 AM to 5:00 PM. (Section incorporated by Article 8 of Provision No. 6550/2008 of the National Administration of Drugs, Food and Medical Technology B.O. 7/11/2008, See Article 9 of the same regulation)

INFORMED and VOLUNTARY CONSENT TO PARTICIPATE IN THIS STUDY

Endovascular Treatment of Communicating Hydrocephalus with the eShunt System

Date of Birth (day/month/year) _____ / _____ / 20 _____

Last Name: _____ First Name: _____

DNI: _____

Address: _____

_____

Telephone Number: ( ) _____

Patient Acknowledgement:

I understand that I have been invited to participate in the investigation of a new device designed to be used in patients who have communicating hydrocephalus.

I sign this Informed and Voluntary Consent Form voluntarily. I am not being coerced by anyone to sign this consent. I have already read, or someone has read the Informed and Voluntary Consent Form to me, and I have already received a copy of this document. I had the chance to discuss with my doctor the clinical trial and to ask him questions. My doubts have been clarified. I have been informed that I can contact my doctor to discuss with him any concern that may come up during the clinical trial. My participation is voluntary, and I can withdraw my consent without jeopardizing my present or future treatment.

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I agree to work together with the doctor and his team and also to participate in all the follow-up visits, as detailed in the information I received.

Participant's full name

_____ _____
Participant's signature Date (written by the participant)

_____
Witness Full Name

_____ _____
Witness Signature Date

_____ _____
Signature and seal of Investigator Date

Lylyk P, *et al. J NeuroIntervent Surg* 2021;0:1–6. doi: 10.1136/neurintsurg-2021-018136

Felipe C. Albuquerque, M.D.
Editor-in-Chief
Journal of NeuroInterventional Surgery
Barrow Neurological Institute
Phoenix, AZ, USA

August 14, 2021

Dear Dr. Albuquerque,

The patient described in this case report unfortunately passed away, accordingly, no consent form could be signed by the patient before death. Many efforts were undertaken to track a family member to approve the JNIS patient consent form but these were unsuccessful.

We hope that the editorial team considers the relative importance and value of disseminating the contents of the report to *JNIS* readership and we have attached as alternatives, a copy of the proof of enrollment of the patient in the ETCHES study as well as the study protocol itself which describes that results of the study may be shared with the scientific community and to which the patient consented during enrollment.

Thank you,

Adel M. Malek for the authors

Adel M. Malek, MD, PhD
Department of Neurosurgery
Tufts Medical Center
Boston, MA, USA

ICMJE DISCLOSURE FORM

Date: 10/10/2021

Your Name: Bleise Carlos

Manuscript Title: First-in-Human Endovascular Treatment of Hydrocephalus with a Miniature Biomimetic Trans-Dural Shunt.

Manuscript Number (if known): neurintsurg-2021-018136.R1

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	**Specifications/Comments (e.g., if payments were made to you or to your institution)**
Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) **No time limit for this item.**	☒ None	
			Click the tab key to add additional rows.
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	☒ **None**	
3	Royalties or licenses	☒ **None**	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	☒ **None**	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	☒ **None**	
6	Payment for expert testimony	☒ **None**	
7	Support for attending meetings and/or travel	☒ **None**	
8	Patents planned, issued or pending	☒ **None**	
9	Participation on a Data Safety Monitoring Board or Advisory Board	☒ **None**	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	☒ **None**	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	☒ **None**	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	☒ **None**	
13	Other financial or non-financial interests	☒ **None**	

Please place an "X" next to the following statement to indicate your agreement:

☒ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 10/10/2021

Your Name: Ivan Roman Lylyk

Manuscript Title: First-in-Human Endovascular Treatment of Hydrocephalus with a Miniature Biomimetic Trans-Dural Shunt.

Manuscript Number (if known): neurintsurg-2021-018136.R1

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

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Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) **No time limit for this item.**	☒ None	
			Click the tab key to add additional rows.
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	☒ **None**	
3	Royalties or licenses	☒ **None**	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	☒ **None**	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	☒ **None**	
6	Payment for expert testimony	☒ **None**	
7	Support for attending meetings and/or travel	☒ **None**	
8	Patents planned, issued or pending	☒ **None**	
9	Participation on a Data Safety Monitoring Board or Advisory Board	☒ **None**	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	☒ **None**	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	☒ **None**	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	☒ **None**	
13	Other financial or non-financial interests	☒ **None**	

Please place an "X" next to the following statement to indicate your agreement:

☒ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 10/10/2021

Your Name: Pedro Lylyk

Manuscript Title: First-in-Human Endovascular Treatment of Hydrocephalus with a Miniature Biomimetic Trans-Dural Shunt.

Manuscript Number (if known): neurintsurg-2021-018136.R1

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The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

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Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) **No time limit for this item.**	☒ None	
			Click the tab key to add additional rows.
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	☒ **None**	
3	Royalties or licenses	☒ **None**	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	☒ **None**	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	☒ **None**	
6	Payment for expert testimony	☒ **None**	
7	Support for attending meetings and/or travel	☒ **None**	
8	Patents planned, issued or pending	☒ **None**	
9	Participation on a Data Safety Monitoring Board or Advisory Board	☒ **None**	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	☒ **None**	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	☒ **None**	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	☒ **None**	
13	Other financial or non-financial interests	☒ **None**	

Please place an "X" next to the following statement to indicate your agreement:

☒ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 10/10/2021

Your Name: Pedro Nicolas Lykyk

Manuscript Title: First-in-Human Endovascular Treatment of Hydrocephalus with a Miniature Biomimetic Trans-Dural Shunt.

Manuscript Number (if known): neurintsurg-2021-018136.R1

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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3	Royalties or licenses	☒ **None**	

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4	Consulting fees	☒ **None**	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	☒ **None**	
6	Payment for expert testimony	☒ **None**	
7	Support for attending meetings and/or travel	☒ **None**	
8	Patents planned, issued or pending	☒ **None**	
9	Participation on a Data Safety Monitoring Board or Advisory Board	☒ **None**	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	☒ **None**	

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11	Stock or stock options	☒ **None**	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	☒ **None**	
13	Other financial or non-financial interests	☒ **None**	

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ICMJE DISCLOSURE FORM

Date: 10/10/2021

Your Name: Scrivano Esteban

Manuscript Title: First-in-Human Endovascular Treatment of Hydrocephalus with a Miniature Biomimetic Trans-Dural Shunt.

Manuscript Number (if known): neurintsurg-2021-018136.R1

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3	Royalties or licenses	☒ **None**	

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4	Consulting fees	☒ **None**	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	☒ **None**	
6	Payment for expert testimony	☒ **None**	
7	Support for attending meetings and/or travel	☒ **None**	
8	Patents planned, issued or pending	☒ **None**	
9	Participation on a Data Safety Monitoring Board or Advisory Board	☒ **None**	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	☒ **None**	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	☒ **None**	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	☒ **None**	
13	Other financial or non-financial interests	☒ **None**	

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ICMJE DISCLOSURE FORM

Date: 11/1/2021

Your Name: Brandon M. Beneduce

Manuscript Title: First-in-Human Endovascular Treatment of Hydrocephalus with a Miniature Biomimetic Trans-Dural Shunt.

Manuscript Number (if known): neurintsurg-2021-018136.R1

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Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) **No time limit for this item.**	☐ None	
		CereVasc, Inc.	Employment, payments to me
			Click the tab key to add additional rows.
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	☒ **None**	
3	Royalties or licenses	☒ **None**	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	☒ **None**	
		CereVasc, Inc.	Payments to me
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	☒ **None**	
6	Payment for expert testimony	☒ **None**	
7	Support for attending meetings and/or travel	☐ **None**	
		CereVasc, Inc.	Reimbursement for costs associated with meeting attendance
8	Patents planned, issued or pending	☒ **None**	
9	Participation on a Data Safety Monitoring Board or Advisory Board	☒ **None**	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	☒ **None**	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	☐ **None**	
		CereVasc, Inc.	Stock options to me
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	☒ **None**	
13	Other financial or non-financial interests	☒ **None**	

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Date: 10/10/2021

Your Name: Adel M. Malek MD PhD

Manuscript Title: First-in-Human Endovascular Treatment of Hydrocephalus with a Miniature Biomimetic Trans-Dural Shunt.

Manuscript Number (if known): neurintsurg-2021-018136.R1

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		CereVasc Inc.	Provided study materials and training for performance of the procedure. It will support article processing charges.
			Click the tab key to add additional rows.
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	☒ **None**	
3	Royalties or licenses	☒ **None**	
		CereVasc Inc.	Royalties from device described in the manuscript, none received so far

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	☐ **None**	
		CereVasc Inc.	Consultant for device design and development
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	☒ **None**	
6	Payment for expert testimony	☒ **None**	
7	Support for attending meetings and/or travel	☐ **None**	
		CereVasc Inc.	Travel and meeting expenses
8	Patents planned, issued or pending	☐ **None**	
		CereVasc Inc.	Patents related to device
		Tufts Medical Center	Patents unrelated to current manuscript
9	Participation on a Data Safety Monitoring Board or Advisory Board	☐ **None**	
		CereVasc Inc.	Chair of study advisory board
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	☒ **None**	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	☐ **None**	
		CereVasc Inc.	No current cash value
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	☒ **None**	
13	Other financial or non-financial interests	☒ **None**	

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Date: 10/10/2021

Your Name: Carl B. Heilman MD

Manuscript Title: First-in-Human Endovascular Treatment of Hydrocephalus with a Miniature Biomimetic Trans-Dural Shunt.

Manuscript Number (if known): neurintsurg-2021-018136.R1

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7	Support for attending meetings and/or travel	☐ **None**	
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8	Patents planned, issued or pending	☐ **None**	
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		CereVasc Inc.	Chair of study advisory board
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	☒ **None**	

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		CereVasc Inc.	No current cash value
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