Official Title: Phase I study to examine the safety and efficacy of allogeneic MSCs in suppressing inflammation in patients with small abdominal aortic aneurysm (AAA)

ClinicalTrials.gov Identifier: NCT02846883

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A Phase I study to examine the safety and efficacy of allogeneic Mesenchymal Stromal Cells in suppressing inflammation in patients with small abdominal aortic aneurysm (AAA); IRB#1510579216

What We are Researching: This research project is hoping to find out if taking a special kind of cells from a healthy human being and injecting them into people with an abdominal aortic aneurysm will decrease inflammation and slow down the enlargement of their aneurysm.

Why You: You have an abdominal aortic aneurysm discovered on the scan requested by your doctor.

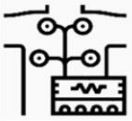
Do You Have to Participate: No, participation is voluntary. You may choose to take part in this research or even leave the study at any time after you choose to take part. Your choice will not change the benefits to which you are entitled and will not affect your relationship with Roudebush VAMC or IU Health.

If you choose to participate in this research project, this is what we will ask you to do and what that means for you:

PROCEDURES

Physical exams and medical history collection

Blood draws to test your blood



Electrocardiogram (ECG) to check your heart function

PET / CT scans to check the size and shape of your aneurysm

Ultrasound to monitor the size of your aorta

Cell Infusion Procedure

RISKS

Accessing your medical records has the risk of a potential loss of confidentiality.

Blood Draws have the risk of discomfort, bruising, infection, excess bleeding, clotting and fainting.

ECG has the risk of slight discomfort from the adhesive patches.

PET / CT scans has the risk of radiation exposure; risk of an allergic reaction from the dye injection and the dye can also cause injury to the kidneys.

There are no known risks to ultrasounds.
Cell Infusion Procedure has the risk of fever, rash, rapid (fast) heart rate, or shortness of breath.

WHERE & HOW LONG

Procedures for veterans will take place at Roudebush VAMC and for non-veterans at IU Health Methodist Hospital.

Your overall participation will last five years.

There is no payment for your participation, but you will receive meal vouchers and your travel may be covered.

If you have questions, please contact Dr. Michael Murphy at 317-988-4049.

BENEFITS OF PARTICIPATING IN THIS RESEARCH: A possible benefit of your participation in this study is the slowing of your aneurysm's growth; however, you may not benefit at all.

Please review the Informed Consent Statement for details about these topics and additional things you should know before making a decision about whether to participate in this study.

Subject Name:		**Date:**
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Sponsor:	VAMC	
Principal Investigator:	Michael P. Murphy, MD	**VAMC:** Roudebush VA Indianapolis

You are invited to participate in a research study to determine the safety and explore the effectiveness of allogeneic (not your cells but those of another human) mesenchymal stromal cells (MSCs) in decreasing inflammation and possible enlargement of your abdominal aortic aneurysm. You were selected as a possible subject because you have an abdominal aortic aneurysm discovered on the ultrasound or computed tomographic ("CT") scan requested by your doctor. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

Michael P. Murphy, MD, Indiana University, Department of Surgery, and Richard Roudebush VAMC and IU Health Methodist Hospital are conducting the study. The purpose of this study is to collect information that will be used to determine if MSCs can be used to decrease inflammation and possibly slow down enlargement of your aneurysm. We will also be collecting blood samples to study special inflammatory cells that cause aneurysms as well as asking you to have an abdominal "PET" (positron emission tomography) scan that can measure inflammation directly in your aneurysm. Dr. Murphy has no financial relationship with the design, conduct or outcome of this study. Dr. Murphy is acting as the Principal Investigator for this study and will not receive salary support for his time commitment to the study.

If you currently have malignant cancer of any kind or if you have had malignant cancer within the last 5 years that has been untreated, except basal cell skin carcinoma, you cannot take part in this study.

Purpose of study and how long it will last:

The purpose of this study is to determine the safety and explore the effectiveness of MSCs given through a vein in your arm into your circulation. The study doctor is researching this method for decreasing the activity of certain inflammatory cells called T cells and B cells and increasing the activity of anti-inflammatory "Regulatory" cells to see if this procedure can help decrease inflammation and enlargement of your aneurysm. Our research has shown MSCs can prevent aneurysm enlargement in mouse models. This will be the first study to see if MSCs can do the same in humans. The allogeneic MSCs will be donated by a healthy volunteer from Case Western Reserve University in Cleveland, Ohio. The Case Comprehensive Cancer Center (CCCC) at Case Western Reserve University is located at WRB 6-303 2103 Cornell Road Cleveland, Ohio 44106. The MSCs will be delivered to the IU Health University Hospital Cell Therapy Lab in Indianapolis, IN. The frozen sample of MSCs will be thawed and delivered to the SICU at the Roudebush VA Hospital, where your infusion of these cells will take place.

Description of the study including procedures to be used:
If you agree to participate, you will be one of up to 50 people who will participate in this study.

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If you agree to be in the study, you must sign this consent form prior to undergoing any study related procedures. If you agree to participate in the study, the following things will happen:

You will be randomized into one of three different time treatment groups based on MSC dose or placebo. Group 1 will receive 1 million MSCs per kilogram of your body weight intravenously, Group 2 will receive 3 million MSCs per kilogram of your body weight intravenously, and Group 3 will receive the placebo (control) which is the solution the MSCs are stored in, called Plasmalyte A. Randomization means that you are placed in a group by chance (like flipping a coin). You will not have a choice into which group you are placed, but you have a 66% chance that you will be in one of the MSC treatment groups. At your Month 24 follow-up visit, you will have the option to be unblinded from your study treatment group.

The following evaluations will be carried out at the baseline screening visit to determine if you are eligible for the study. A study calendar is also included later in this consent which shows the study procedures and the timing of those procedures.

Baseline screening includes:

- Complete medical history and physical exam. Your medical history includes: your current medications and medications you have taken in the past 30 days; all medical problems that you have now or used to have; all surgeries and procedures that you have had; and information about you such as age, gender, race, height/weight.
- Vital signs (such as blood pressure, heart rate, respiratory rate, temperature)
- Pregnancy test for women of childbearing age;
- Blood tests (complete blood count, serum chemistry, liver panel, lipid panel, infectious disease testing, hs-CRP, CPK, HLA typing) will be obtained to make sure you do not have current infection, and to make sure your kidneys and other organs are functioning normally.
- Electrocardiogram (ECG) to check your heart function;
- 18-fluorodeoxyglucose Positron Emission Tomography/Computed Tomography (PET/CT) scan to measure the inflammation of your aneurysm at baseline and Day 14 to monitor the size of your aneurysm. You will have CT Angiograms annually from Month 12 through the end of your participation at Month 60. Annual CT Angiograms are considered standard of care.
- Duplex ultrasound of your aorta at baseline and every 6 months while you are enrolled in this study to monitor the size of your aneurysm.
- Current medication list.

- If you are on a blood thinner medication, a pre-operative blood test to check your blood clotting ability will be performed. This will require approximately one teaspoon of blood drawn from a vein in your arm.

The baseline procedures may take most of the day (approximately 4 to 5 hours) and will take place at the Roudebush VA Hospital if you are a veteran or IU Health Methodist Hospital if you are not a veteran.

Veterans will be admitted to Richard L. Roudebush VA Hospital for the infusion of the mesenchymal stromal cells and stay in the SICU for up to 2-4 hours, until the assessments have been completed. The study doctor will assess you before you are discharged home. If you are a veteran, all study visits will occur at the Richard L. Roudebush VA Hospital, Indianapolis, Indiana.

If you are **not** a veteran, the infusion procedure will take place at the Clinical Research Center at IU Health University Hospital, 5050 University Blvd., Indianapolis, IN. This will be the only study visit that will occur at University Hospital; all other study related visits and procedures will take place at IU Health Methodist Hospital.

Mesenchymal Stromal Cell Infusion Procedure:
Depending upon the group to which you are assigned, we will infuse allogeneic (cells that are not your own) mesenchymal stromal cells (MSCs), or a solution of Plasmalyte A (placebo) intravenously into a vein in your arm. MSCs will circulate through your bloodstream where they will release signals that turn off inflammation and injury. This infusion procedure will be performed over 30-45 minutes while we monitor your heart rate and rhythm, blood pressure, and breathing, including oxygen levels (pulse oximetry). This monitoring will require attachment of pads to your chest, a blood pressure cuff on your arm, and a pulse oximeter on your fingertip. Before the infusion procedure, up to 34 milliliters of blood, about 2.5 tablespoons will be drawn from a vein for laboratory analysis. Blood will be drawn up to 12 times (approx. 2 cups total over a duration of 5 years) throughout the course of your participation in the study. After the infusion is complete, you will be monitored for an additional two hours, then discharged home.

A portion of the blood sample collected at each time point will be sent to a laboratory directed by Dr. Phillip Yang, MD, Professor of Medicine, Division of Cardiology. This lab is located at 300 Pasteur Drive, a260 Palo Alto, California, 94304. Your samples will not be identifiable which means that researchers will not have any personal identifiable information to link your sample to your health records, nor will they know to which you will be randomized. After laboratory analysis, your sample will be discarded and no portion will be stored or banked for future use in research.

We will follow your health for 5 years to see if you have developed any problems after MSC administration and to see if we can determine if MSCs have had any effect in decreasing inflammatory cell numbers in your

circulation as well as decreasing inflammation in your aneurysm. After your 5-year follow-up visit, you will have completed participation in the study; however, because of the possibility that your aneurysm may enlarge you need to follow-up with your private physician after your participation in the study ends.

It is important for you to follow the directions for treatment and the study. The study requires you to return to the study doctor for follow-up evaluations of your progress at days 7, 14 and months 1, 6, 12, 18, and 24. You will also return to the VAMC in Indianapolis at 6-month intervals through your 5-year visit. Screening and follow-up visits will take place at the Peripheral Vascular Clinic located on the first floor of the Richard Roudebush Veterans Administration Center, 1481 West 10th Street, Indianapolis, IN 46202.

For Non-Veterans, screening and follow up evaluations will take place in the Vascular Clinic at IU Health Methodist Hospital, 1801 N. Senate Blvd., Indianapolis, IN 46202. Evaluation of your progress at days 7, 14 and months 1, 6, 12, 18, and 24 will be completed at IU Health Methodist Hospital. You will also return at 6-month intervals through your 5-year visit.

Calendars have been inserted below so that you can see the number of study visits you will have and the time intervals.

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Principal Investigator:	Michael P. Murphy, MD	**VAMC:** Roudebush VA Indianapolis

Follow-Up Schedule

Procedures	Baseline	Day 0 MSC (2-4 hr)	Day 7 F/U (+/-2 days)	Day 14 F/U (+/- 5 days)	Mo 1 F/U (+/- 1wk)	Mo 6 F/U (+/- 2wk)	Mo 12 F/U (+/- 2wk)	Mo 18 F/U (+/- 2wk)	Mo 24 F/U (+/-4wk)
Informed Consent	X								
Medical History	X								
Physical Exam	X	X	X	X	X	X			
Vital Signs	X	X	X	X	X	X	X	X	X
Con. Medications	X	X	X	X	X	X	X	X	X
AE/SAE Evaluations	X	X	X	X	X	X	X	X	X
QoL Questionnaires	X					X	X	X	X
Infectious Disease Labs	X								
Laboratory Evaluations	X				X				
12 Lead ECG	X				X				
Duplex U/S	X					X	X	X	X
Randomization	X								
PET/CT	X			X					
CT Angiogram							X		X
Blood Sample		X	X	X	X	X	X	X	X
Infusion Reaction Assessment		X		X					

Long-Term Follow-Up Schedule

	Mo 30 (+/-4wks)	Mo 36 (+/-4wks)	Mo 42 (+/-4wks)	Mo 48 (+/-4wks)	Mo 54 (+/-4wks)	Mo 60 (+/-4wks)
Duplex Ultrasound	X	X	X	X	X	X
CT Angiogram		X		X		X
QOL Questionnaire	X	X	X	X	X	X
AE/SAE Evaluations	X	X	X	X	X	X
Blood Sample	X	X	X	X	X	X

Risks:
While on the study, the risks are:

Cell Infusion
Risks associated with MSC infusion are fever, rash, rapid heart rate, or shortness of breath. These risks are rare and you will be given medication (Benadryl) to prevent these risks. Your heart rate and rhythm as well as breathing and blood oxygen level will be monitored during and after the MSC infusion process to recognize these rare risks.

Blood Draws

Risks associated with drawing blood from your arm include minimal discomfort and/or bruising. Infection, excess bleeding, clotting, and fainting are also possible, although unlikely. In order to minimize these risks, blood will be drawn by experienced technicians.

ECG
You may experience slight discomfort when the adhesive patches are removed. Care will be taken when removing the adhesive patches to reduce your discomfort.

18F-fluorodeoxyglucose (FDG) uptake with positron emission tomography/computed tomography (PET/CT).

18-FDG PET/CT is performed two times during this study. Each test involves exposure to radiation. Your participation in this research study involves exposure to radiation in addition to what you may receive as part of your standard care. The benefit from the radiation you receive for your standard care typically outweighs the risk because it allows your doctor to provide appropriate medical care; however, the additional radiation "dose" you receive for research purposes may not benefit you personally. Regulatory agencies have established annual radiation dose limits for both individuals who work with radiation (e.g. x-ray technologists, radiologists, etc.) and those participating in research studies. If you decide to participate in this research study, the radiation dose you receive will be below the annual limit for radiation workers.

Radiation has been shown to cause cancer and/or leukemia from doses that are significantly higher than the additional annual radiation dose you will receive by participating in this study. According to the Health Physics Society (an international organization that specializes in radiation protection), the increased risk of health effects (i.e. cancer and/or leukemia) from radiation doses of this amount is either too small to be observed or nonexistent in a normal population. While there is no evidence that any risk exists for humans exposed to such low levels, it is assumed that the risks rise with lifetime accumulated dose from all sources of ionizing radiation, including the doses you receive from medical procedures and the environment. You should also be aware that everyone's sensitivity to radiation is not the same and some diseases (e.g. genetic diseases, diseases affecting DNA repair, and immune diseases such as HIV) may make you more sensitive to the effects and consequences of the radiation exposure than the normal population. Finally, you should know that even if there is an increased risk of an effect, it could be 5 to 20 years before any effect would actually occur. Thus, you may want to factor in your age, overall health, and the number of medical radiation procedures that you've had when determining if this risk is acceptable to you. The calculated effective dose resulting from your participation in this study is available upon request.
There is a risk of an allergic reaction, which may be serious, whenever contrast material containing iodine is injected. A patient with a history of allergy to x-ray dye may be advised to take hydrocortisone and Benadryl for 24 hours before 18-FDG PET/CT to lessen the risk of allergic reaction or advised to not participate in the study.

Contrast can also cause injury to the kidneys and so patients with impaired kidney function will be excluded from enrollment.

Computerized tomography (CT) scan

This test can provide clear images of your aorta, and it can detect the size and shape of an aneurysm. This annual test is considered normal "Standard of Care."

During a CT scan, you lie on a table inside a doughnut-shaped machine. CT scanning generates X-rays to produce cross-sectional images of your body. Doctors may inject a dye into your blood vessels that helps your arteries to be more visible on the CT pictures (CT angiography).

During a CT scan, you are briefly exposed to ionizing radiation. The amount of radiation is greater than you would get during a plain X-ray because the CT scan gathers information that is more detailed. CT scans have not been shown to cause long-term harm, although there may be a very small potential to increase your risk of cancer. CT scans have many benefits that outweigh this small potential risk. Doctors use the lowest dose of radiation possible to obtain the needed medical information.

You will receive a special dye called a contrast material through a vein in your arm before your CT scan. Although rare, the contrast material can cause medical problems or allergic reactions.

There is a risk of an allergic reaction, which may be serious, whenever contrast material containing iodine is injected. Most reactions are mild and result in a rash or itchiness. In rare instances, an allergic reaction can be serious, even life threatening. Contrast can also cause injury to the kidneys and so patients with impaired kidney function will be excluded from enrollment.

Other Risks:
There also may be side effects that we cannot predict.
If you feel that you are experiencing problems directly related to the study treatment, you should tell the study doctor immediately. If you cannot do this because it is an emergency, you should get treatment and tell the study doctor as soon as possible.

Confidentiality:
There is a risk of loss of confidentiality.

Payment:
You may receive compensation for travel related expenses. If you are a veteran and your visits take place at the Roudebush VAMC, you will receive a meal voucher in the amount of $6.00 before each of the first three CT

visits. If you do not have transportation and live within 60 miles of the VA or IUH Methodist Hospitals you will be offered roundtrip, prepaid Lyft or Uber transportation for each of the first 5 study visits: Baseline through Month 1 visits. If you provide your own transportation to the VA or IUH Methodist Hospital you will be given a $30 gift card for each of the first 5 study visits: Baseline through Month 1 visits.

Benefits:
You may or may not benefit from taking part in this study. The possible benefits you may have from being in this study include the possibility of slowing your aneurysm's growth. The information that we gather will help us learn more about stem cell therapy and could help patients in the future.

Alternate Courses of Action or Treatment:
The alternative to participating in this research study is to continue with supportive measures that include smoking cessation, blood pressure control, and an exercise program. Your doctor will discuss these alternatives with you.

Medical Results:
We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, this information will be provided to you. This information may include laboratory results or results of a CT scan. This information will be provided to you by phone or as soon as possible.

Statement of Use of Research Results:
The results of this study may be published, but your records or identity will not be revealed unless required by law.

You will be told about new information that may affect your health, welfare, or willingness to stay in the study. Your participation may be terminated by the investigator without regard to your consent if he feels that it is in your best interest to do so. In addition, Indiana University, the VA Medical Center, IU Health Methodist Hospital, or the FDA could discontinue further enrollment of people into this study. Should your participation in the study be stopped, a full explanation and possible alternatives will be discussed with you.

Re-contact for Future Use:

In the future, researchers may design a particular research study that requires use of the biological materials you have given as well as additional samples and/or information. If, in the future, we would like to obtain additional samples and/or information, we will need to contact you to request your permission. Please indicate below whether or not you give your permission for us to contact you about obtaining more information.

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I give my permission for researchers to contact me about obtaining additional samples and/or information.

Yes_____ No _____ Initials_____ Date _____

Confidentiality:

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published and databases in which the results may be stored. Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Indiana University or the Roudebush VA Medical Center. For records disclosed outside of Indiana University or the Roudebush VA Medical Center, you will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. Murphy's office or other appropriate research staff.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, , the Indiana CTSI Clinical Research Center (CRC), the Data Safety Monitoring Board (DSMB), the VA Research and Development Committee's designees, and federal agencies, including but not limited to the Office for Human Research Protections (OHRP), the Office of Research Oversight (ORO), VA Office of the Inspector General (OIG), the General Accounting Office (GAO), Food and Drug Administration (FDA), etc., who may need to access your medical and/or research records. When you sign this form, you will be giving permission for these groups to see your confidential information when it is necessary. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

Any documents we copy for this study will remain in your study file at the VA Hospital and will not be removed from the VA Hospital. However, identifiable personal health information will be stored in two databases at Indiana University. These two databases (one called Redcap and one called Oncore) are password protected, and no one other than study team personnel or authorized administrators can access your information stored in these databases.

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Retention of Research Records:

Research records will be maintained by the investigator in accordance with the VHA Records Control Schedule.

CLINICAL TRIAL POSTING
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

Research Subject Costs:

1. There will be no costs to you for any of the treatment or testing done as part of this research study. Eligibility for medical care at a VA Medical Center is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.
2. The study is sponsored by the principal investigator, Dr. Michael P. Murphy.
3. You will not be required to pay for medical care or services received as a subject in a VA research project except as follows:
   Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are **not** part of this study.

Compensation & Treatment for Injury:

1. You will not receive payment for taking part in this study.
2. The VA medical facilities shall provide necessary medical treatment to a research subject injured as a result of participation in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees. This does not apply to (1) treatment for injuries due to noncompliance by a subject with study procedures; or (2) research conducted for VA under a contract with an individual or a non-VA institution.
3. Financial compensation for research-related injuries is not available. However, by signing this form, you do not give up your legal rights to seek such compensation through the courts.
4. You will be provided three meal vouchers for use at the VA during the study. These are for a late breakfast or early lunch on the three visits you will have a CT scan.

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VOLUNTARY NATURE OF STUDY:

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with the Roudebush VA Medical Center or Indiana University. If you withdraw from the study, no new information about you will be collected for study purposes unless the information concerns an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. If you choose to withdraw from the study, we ask that you do so in writing to Dr. Michael Murphy, Richard L. Roudebush VA Medical Center, 1481 W. 10th Street, Room D3009, Indianapolis, Indiana 46202. However, if you choose to withdraw from the study by telling us on the phone or in person, we will honor that as well.

Your participation may be terminated by the investigator without regard to your consent if he feels that it is in your best interest to do so. In addition, Indiana University or the FDA could discontinue further enrollment of people into this study. Should your participation in the study be stopped, a full explanation and possible alternatives will be discussed with you.

RESEARCH SUBJECT'S RIGHTS:

Participation in this study is entirely voluntary. You may refuse to participate. Refusal to participate will involve no penalty or loss of rights to which individuals are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits. You will receive a copy of this signed consent form.

In case there are medical problems or questions, Dr. Michael Murphy can be called at 317-988-4049 during the day and after hours you may call 317-554-0000 and ask for Dr. Murphy to be paged or ask for the Vascular Surgeon on call to be paged. If any medical problems occur in connection with this study, the VA will provide emergency care.

Please direct questions about the consent process and the rights of research subjects to the VA Customer Service Office at (317) 988-2602. For questions about your rights as a research subject or complaints about a research study, contact the Indiana University Human Subjects Office at 317-278-3458 or 800-696-2949. If you have any questions about the research study or want to check the validity, discuss problems, concerns or obtain information or offer input, please call the VA Research Personnel Office at 317-988-3032.

Department of Veterans Affairs	**VA Research Consent Form**

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Principal Investigator:	Michael P. Murphy, MD	**VAMC:** Roudebush VA Indianapolis

The study has been explained to me and all of my questions have been answered. The risks or discomforts and possible benefits of the study have been described. Other choices of available treatment have been explained.

_____	_____	_____
Subject's Signature	Printed Name of Subject	Date
_____	_____	_____
Signature of Person Obtaining Consent	Printed Name of Person Obtaining Consent	Date