Consent to Participate in Research

Study Title: Understanding the Patient-Centered Outcomes for One-stage and Two-stage Brachial-Basilic Arteriovenous Fistulas: A Pilot Trial

Principal Investigator: Tze-Woei Tan MD

Sponsor and/or Funder: ASDIN

Summary of the research

This is a consent form for participation in a research study. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate. Feel free to discuss the study with your family and/or friends. When all of your questions have been answered, you can decide whether or not you want to take part in this study. You will be given a copy of this consent form for your records.

You have been invited to participate in this study because you are receiving hemodialysis with a central venous catheter (CVC) and are scheduled to have a new upper arm Brachial-basilic arteriovenous fistula or (BBAVF) procedure. This procedure (Brachial-basilic arteriovenous fistula) is done in either one stage or in two stages. The one stage procedure is completed in one surgery while the two stage procedure is two different surgeries 6-8 weeks apart. Your doctor believes that you are a candidate for either the one or the two stage procedure. The risks of participating in this trial are minimal. You are already scheduled to have a BBAVF procedure as standard of care. The decision for which type of surgery you will have is typically done by your doctor. If you choose to sign this consent, you are agreeing to be randomized to one of the two procedures available. Half of the participants in this study will have the one stage procedure and half will have the two stage procedure, two separate surgeries 6-8 weeks apart. The assignment of this treatment is purely by chance (50/50, just like a coin toss).

The randomization to the procedure is not blinded and will be known to you and your surgeon before your surgery. The risks for both procedures are found under the risk section of this consent, and you will be able to ask the doctor any question you may have about the surgeries prior to signing this consent form.

This study will last approximately one year with study visits at consent (this visit), at baseline (pre-procedure), and by phone at 6 and at 12 months post procedure. All visits will be standard of care with the addition of study related questionnaires at your pre-surgery (baseline) visit, 6 month and 12 month study visits. We will also be collecting demographic data (age, birthdate, medical record number) your current medications, vascular history related to your hemodialysis, details of your surgery and fistula status at the end of your surgery. This

information will be collected to help us understand your current medical status and surgical outcome.
We are doing this study to learn more about the surgical outcomes of each type of procedure and understand the patient's perspective after having had one of these two procedures.
As a result of this study, we are hoping that in the future we may be able to incorporate the patient's perspective in the discussion of treatment options prior to surgery.

The University receives compensation from the sponsor of this study for the conduct of this study. If you have any questions, please discuss this with your study doctor.

Why is this study being done?

This study is being done to help us understand the patient perspective of these two procedures. We are hoping that by gaining knowledge of patient centered outcomes we can better incorporate the patients preference into the pre-surgery discussion. We would like to use the results of this pilot trial to design a larger study to help decide the best surgical procedure for a BBAVF and include the perspective of the patients.

What will happen if I take part in this study?

If you are eligible for the study and agree to participate, you will be assigned by chance (like flipping a coin) to either Group A (one stage procedure) or Group B (two stage procedure). Neither you nor your doctor can control the group to which you will be assigned.
Prior to your procedure, you will have routine pre-operative tests (part of standard care), as determined by you and your doctor. All other aspects of your surgical treatment, including admission to the hospital, hospital stay, anesthesia, and your post-operative visits are part of your routine care and not performed specifically for the purposes of this research study.
Specific visits for the research study are described below:
Screening Visit:

- Be given informed consent, discuss with study team
- If you decided to participate in the study you will then have a Baseline visit before your surgery

Baseline Visit:
You will be asked to return to the clinic where you will meet with the study team, answer the PROMIS/CAT questionnaires and learn about which of the procedures you receive.
Follow-up Visits:
The next study visits will be at 6 months and 12 months after your surgery (approximately 60-90 minutes each in a phone call with study staff)**.**
At each of your visits, we will collect information about your:

- Current signs and symptoms.
- Current medications.
- Physical examinations, body weight, heart rate, and blood pressure.
- Any hospitalizations you have had since your surgery

How long will I be in this study?

Your participation will last approximately one year. If you choose to participate in this study, the day you sign consent will be your screening day, there will be a baseline (pre-surgery) visit, and a 6 and 12 month post-surgery visit which consists of answering questionnaires over the phone. Each of those visits will last 60-90 minutes.

How many people will take part in this study?

Approximately 60 people will be enrolled in this study at Banner University Medical Center Tucson and 5 other study sites. Approximately 10 people will be enrolled at Banner University Medical Center Tucson.

What benefits can I expect from being in this study?

There is no expected benefit to you from being in this study except to help us understand the perspective of a patient regarding these procedures.

What risks, side effects or discomforts can I expect from being in the study?

There are risks associated with any operation or procedure. We cannot be sure how your body may respond. There is a chance that you may experience one or more of the risks and/or discomforts listed below from the fistula creation procedure you receive; you may also experience a risk that is currently unknown. Before they perform the procedure, the doctor will discuss with you the risks that are associated with the specific procedure that you will receive. Below are the main risks associated with these surgeries:

The most common surgical risks for both procedures are:

- Wound infection
- Bleeding
- Fistula Thrombosis or blood clot
- Steal Syndrome: this is caused when there is not enough blood flow through the fistula
- Arm swelling: when a fistula is created blood flows directly from an artery into a vein, bypassing some capillaries. When this happens, tissues below those capillaries receive a smaller amount of blood and that results in swelling
- CVC (central venous catheter) related bacteremia (infection) for the two stage surgery

To the best of our ability, any significant new findings that become available during the research study will be made known to you.

What other choices do I have if I do not take part in this study?

Your participation in this study is voluntary. If you choose to participate you may leave the study at any time. No matter what decision you make, there will be no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without any penalty or loss of your usual benefits. The only alternative to participating in this study is not to participate. You will still have the BBAVF procedure that your doctor has discussed with you.

When may participation in the study be stopped?

You may choose to stop your participation in this study at any time. Your decision to stop your participation will have no effect on the quality of medical care that you receive. You may be withdrawn from the study if, in the judgment of your study doctor, it is in your best interest. After withdrawing, no new information about you will be collected for study purposes unless information is about an event that is related to the study.

What happens if I am injured because I took part in this study?

The sponsor of this research ASDIN. If you are injured or become ill as a result of research procedures, medical treatment will be provided to you but the sponsor and the University of Arizona will not pay for this treatment. If any research activity results in injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries may be billed in the ordinary manner to you or your insurance company.
This, however, does not waive your rights in the event of negligence. If you suffer an injury from participating in this study, you should seek treatment. The University of Arizona and Banner University Medical Group have no funds set aside for the payment of treatment expenses for this study.
If you think that you have suffered a research related injury, let the study physicians know right away. Dr. Tze-Woei Tan at 520-305-9393
The University of Arizona and Banner-University Medical Center have no funds set aside for the payment of treatment expenses for this study.

What are the costs of taking part in this study?

This is not a treatment study. You will be having a surgical procedure that you would be having whether or not you participate in this trial. Routine medical care performed while participating in study will be billed to you and / or your insurance company. This will include (but is not limited to) your BBAVF surgery, all lab work, vein mapping, physical exam and all surgery related protocols, administration of medications, and any related treatment of side effects. The randomization, follow-up questionnaires and data collection performed for research only will be provided at no charge to you or your insurance company. Not all insurance companies are willing to pay for services performed in a clinical trial. You will be responsible for any charges that your insurance does not cover including regular co-payments and deductibles. Please speak with your insurance company to find out what you may be financially liable for.

Will I be paid for taking part in this study?

There is no monetary compensation for participating in this study.

Will my data or specimens be stored for future research?

This is a pilot study looking at two different sets of data. One set is looking at the outcomes of the two types of procedures and the other set will look at patient preference. If this study yields significant results, the data from this study may be used to support additional funding for a larger study. If that happens all data will be coded and used in data sets, such as age range, race/ethnicity blocks. the information may be used to support future research studies without additional informed consent. This information will be stored in RedCap and will only be shared in support of future funding.

Will I hear back on any results that directly impact me?

Given the small number of patients it is unlikely that any results will be known prior to the completion of the study, however, to the best of our ability, any significant new findings that become available during the research study will be made known to you.

Will my study-related information be shared, disclosed, and kept confidential?

Your privacy is important. Efforts will be made to protect the identities of the participants and the confidentiality of the research data used for this study. All information gathered in this study will be kept private according to all applicable laws and regulations. Your identity as a participant in this study will remain strictly confidential. The information collected for this study will be used only for the purposes of conducting this study. All sensitive patient data, including patient identifiable information (PHI) will be encrypted per University of Arizona standards and stored. The study doctor will ensure that no identifiable information is included in the results or publications.

Because of the nature of the data, it may be possible to figure out your identity; however, there will be no attempt to do so and your data will be reported in a way that will not identify you. Your data will be assigned a unique study identification code. Only study personnel will have access to personal identifying information. This information will be kept locked up and only research personnel will have access to it.

Study data will be kept in a secure RedCap database and questionnaires will be answered on an iPad that is encrypted to the University of Arizona standards and is password protected.

It is anticipated that there will be circumstances where your study related information and Protected Health Information (PHI) will be released to persons and organizations described in this form. If you sign this form, you give permission to the research team to use and/or disclose your PHI for this study. Your information may be shared or disclosed with others to conduct the study, for regulatory purposes, and to help ensure that the study has been done correctly. These other groups may include:

- Office for Human Research Protections, Food and Drug Administration, or other federal, state, or international regulatory agencies
- *Banner University Medical Group and Banner Health*
- The University of Arizona (UA) and the UA Institutional Review Board
- The sponsor and/or funder supporting the study, their agents or study monitors
- Your primary care physician or a specialist taking care of your health.

If you agree to take part in this study a copy of this signed informed consent form will be saved into your electronic medical record (EMR) at Banner Health. As a result, healthcare providers and staff who are not working on this study, but who may provide you medical treatment in the future, will know that you are taking part or took part in this study.

Your PHI may no longer be protected under the HIPAA privacy rule once it is disclosed by the research team.

What study-related information and PHI will be obtained, used or disclosed from my medical record at Banner?

Information related to this research study that identifies you and your PHI will be collected from your past, present, and future hospital and/or other health care provider medical records.

The PHI you are authorizing to be used and/or disclosed in connection with this research study is:

- Age
- Date of Birth
- Gender
- Race/Ethnicity
- Medical record number for chart access will not be disclosed

Medical Records: Medical information, such as operation notes, collected during this study will become part of your hospital medical record only if it is determined to be pertinent to the care you receive at Banner-University Medical Center Tucson (BUMC-T. Medical records are considered permanent records; therefore, materials cannot be deleted from the record. Medical records are available to health care professionals at BUMC-t and may be reviewed by medical staff in the course of carrying out their responsibilities; however, they are required to maintain confidentiality in accordance with applicable laws and BUMC-T policies. Information contained in your medical record may not be given to anyone unaffiliated with BUMC-T in a way that could identify you without your written consent, except as required or permitted by law.

- Past procedure notes
- Diagnostic test results
- Current medical diagnosis

- Demographic information, including date of birth, gender, ethnicity, age.

Demographic information to be disclosed may include, but is not limited to, your name, address, phone number, or social security number. If you receive compensation for participating in this research study, information identifying you may be used or disclosed as necessary to provide that compensation.

Your existing health records may include information related to the diagnosis or treatment of sexually transmitted disease (STD), acquired immunodeficiency syndrome (AIDS), human immunodeficiency virus (HIV), other communicable diseases, genetic information (e.g., genetic testing), and/or alcohol and/or drug abuse. The study staff and study sponsor's monitor may see this information while reviewing your regular health records for this study, but they WILL NOT create, collect, or disclose this type of information for the purposes of this research study.

When will my authorization expire?

There is no expiration date or event for your authorization. Therefore, unless you cancel this authorization (as instructed below) this authorization will continue to be effective.

Do I have to sign this authorization form?

You do not have to sign this authorization. However, if you decide not to sign, you will not be able to participate in this research study; and it will not affect any non-study Banner Health medical treatment or health care, payment, enrollment in any health plans, or benefits.

Also, by signing this form you are authorizing and permitting uses and/or disclosures of your PHI for future research purposes (e.g., future studies) as described in this document. The information gained in this study may be used to apply for a larger study. The information from this study would not use any identifying information.

What do I need to know if I decide to cancel my authorization?

After signing the authorization, you may decide to cancel your previous authorization for the research team to use your PHI. If you cancel the authorization, you will no longer be able to stay in the research study. Please note that any PHI collected before you cancel the authorization may still be used. You may revoke the authorization by contacting the Principal Investigator in writing. Contact information is under "Who can answer my questions about the study" at the end of this document.

Will access be limited to your research study record during this study?

You will not have access to the research information developed as part of this study until it is completed unless information that may impact your participation is identified.

Who can answer my questions about this study?

If at any time you feel you have had a research-related injury, or for questions, concerns, or complaints about the study you may contact ***Dr Tze-Woei Tan at 520-626-6670 or at*** **520-305-9393 (24 hours)**

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program at 520-626-6721 or online at http://rgw.arizona.edu/compliance/human-subjects-protection-program.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact ***Dr Tze-Woei Tan at 520-305-9393 (2 hrs)***.

If you have any questions or concerns about the authorization for access to your PHI, you should contact Sue Colvin, Banner Research Regulatory Affairs Director, at (602) 839-4583 or sue.colvin@bannerhealth.com. You may also request and will be provided a copy of the Notice of Privacy Practices.

To cancel your authorization for access to PHI you must notify the *Principal Investigator* and/or *Research Team* in writing at the following address:

Dr Tze-Woei Tan
Banner University Medical Center Tucson/University of Arizona College of Medicine
1501 N Campbell Ave suite 4402
Tucson Arizona 85724.

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

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study and I authorize the use and/or disclosure of my PHI. I am not giving up any legal rights by signing this form. I will be given a signed copy of this form**.**

Printed name of subject	Signature of subject	Date

Investigator/Research Staff

I have explained the research to the participant or the participant's representative before requesting the signature(s) above. There are no blanks in this document. A signed copy of this form has been given to the participant or to the participant's representative.

Printed name of person obtaining consent	Signature of person obtaining consent	Date