National Taiwan University Hospital Hsin-Chu Branch
Internal Board Review
Research Consent Form

You are invited to join a research. This form is prepared for you to learn the essential materials. The physicians and research staffs will explain the details to you.

Research Title:

A Randomized Trial Comparing Regular Balloon and Regular Balloon for Dialysis Access Stent Graft Restenosis

Designed and performed:
National Taiwan University Hospital Hsin-Chu, Division of Cardiology

Pharmacy: nil

Fund source: National Taiwan University Hospital Hsin-Chu Branch

Principal investigator: Mu-Yang Hsieh, attending physician, division of cardiology, tel: 0972-654046

Research assistant: Miss Wang, 03-5326151-2031

24-hour emergent contact: Dr. Mu-Yang Hsieh, tel: 0972-654046

Patient name:

Gender: Birth date:

MRN:

Contact address:

Telephone:

Surrogate:

Relationship of patient and the surrogate:

Gender: Birth date:

National identification number:

Contact address and telephone:

1. Background:

For treatment of dialysis access stenosis and graft stent restenosis, we now can use

regular balloon, cutting balloon, and drug-coated balloon to treat the vascular lesion (stenosis).

The current 1-year patency rate of regular balloon angioplasty for dialysis access is around 5%. And there is new balloon technology (drug-coated balloon) with batter 1-year patency rate around 35%. But there is no data in regard of in-stent restenosis of dialysis access.

2. Aim:

1. We wish to evaluate the restenosis rate of dialysis access, specifically arteriovenous graft. And compare the treatment efficacy of drug-coated balloon in comparison to regular balloon.
2. We will evaluate the restenosis rate of the in-stent restenosis in dialysis access after drug-coated balloon or regular balloon angioplasty.
3. We will evaluate the vascular lesion with intravascular ultrasound and have detailed vessel measurements.
4. We will establish a database including the treatment result and treatment modality.

3. Inclusion and exclusion criteria:

The research assistant will evaluate your eligibility and discuss the criteria to join this study. You need to know the process and benefit/risk of this study and sign the inform consent before entering this study. We plan to enroll 20 patients.

Inclusion criteria:

1. Age 20-90 years old and received at least 90 days of maintenance dialysis.
2. Received a stent graft for your dialysis access recurrent stenosis.
3. Having a stenotic lesion within 2 cm of stent edge or within the stent.
4. Symptoms of dialysis access malfunction (decrease flow or increased pressure).
5. Patient willing to participate.

Exclusion criteria:

1. Elbow contracture due to fracture.
2. Lesion cannot be crossed with a wire and hence could not perform balloon angioplasty.
3. Allergic to heparin.
4. Bleeding tendency.
5. Already participating in our clinic study.
6. Anticipated shortened life expectancy due to other comorbidity: cancer, liver disease, or terminal heart failure.

7. Patient unwilling to join the study.
8. Adolescence, criminal, pregnant women, psychiatric patient, staffs or students of the researcher.

4. Study methods:

This is a prospective, single blind, single center, randomized study. We aim to compare the efficacy of regular balloon versus drug-coated balloon for dialysis access in-stent restenosis lesion. This study is designed to prove that drug-coated balloon is more efficacious with better and prolonged treatment results. The research staff will key-in your basic data and use a computer to randomize you into two study arms- regular balloon or drug-coated balloon.

We will use a standard approach to perform balloon angioplasty to treat the vascular lesion within you dialysis access. We will also use intravascular ultrasound to study the changes of luminal parameters before and after the angioplasty.

At the moment of joining this study, the research staff will:

1. Record your demographics, dialysis data, habits, drugs in use, and follow your status with chart review.
2. Record your routine blood work-ups done in the hemodialysis room.
3. Follow your status every 6 months.
4. The follow-up length is one year. And we will invite to have angiography and intravascular ultrasound study at 1-month and 3-month.
5. A telephone follow-up will be extended to one year.

With your permission, we will collect 10 ml every year to check the uremic toxin levels.

To protect your privacy, we will use a single number to represent your data. The blood sample will be stored in a -80 centigrade refrigerator for 5 years. If you wish to abandon and discard the blood sample, you may contact us anytime.

If you permit us to store the blood sample and donate it for future research purpose, please sign here:

□ Yes, I agree. Signature: Date:

□ No, I disagree. The sample will be discarded immediately. Signature: Date:

5. Potential adverse effect, its incidence rate, and its management.

The potential adverse effect to balloon angioplasty is already documented in the treatment consent. The incidence rates are identical to that explained in the procedure inform consent.

6. Alternative treatment method

None. Because the balloon angioplasty to stenotic dialysis access has already been established as a standard treatment, there only exists medical treatment as alternative method.

7. Anticipated benefits

You will not obtain additional financial benefits. But we gain a lot knowledge from your treatment response.

8. Contraindications and restraints

If you receive other medications from other hospital, please inform us. We will follow your condition with telephone or contacts to your hemodialysis unit.

9. Confidentiality

National Taiwan University Hospital Hsin-Chu Branch will set a privacy security for your personal data. Your privacy and personal data are protected even the study results are published. You know that after signing this permit, the study steering and safety committee will regular examine for safety and efficacy. Your confidentiality will be guaranteed.

10. Damage and insurance

1. The hospital is responsible for the procedure safety. But the anticipated complication due to procedure is not included.
2. We will provide professional consult for the patient should any damage resulted.
3. Besides the above mentioned 1. and 2., this research will not cover other cost. If you cannot accept, we suggest that you should not join this study.
4. You will not lose any rights by signing this consent.

11. Rights of the patient

1. During the study period, any beneficial information that is related to your health and disease will be actively provided by our staff.
2. If you have any question about your rights, please contact our board review and research unit: 03-5326151-8665.
3. You will be cared by Dr. Mu-Yang Hsieh (0974-654046). The staff will hand you a copy of this consent. By signing the signature, you agree that the research

staff has already provided detailed information about this study.

12. Stop and withdrawal

You can stop and withdrawal from this study anytime without any reason. It will not interfere with future care.

13. Signature

1. The investigator has explained about the study aim, background, and methods. The benefits and risks are also explained.
    1. Signature of the investigator: _____
       Date: _____
2. The study participant has already gained the knowledge of this study (benefits and risks). I here sign and agree to become participated in this study.
    1. Signature of the participant: _____
    2. Signature of the surrogate: _____
    3. Date: _____
    4. Relation of the surrogate to the participant: _____
3. Witness
    1. Name: _____
    2. National identification number: _____
    3. Telephone: _____
    4. Contact address: _____
    5. Relation to the participant: _____

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