PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM
(Clinical intervention research adult subjects)

1 Title of study: A randomized controlled study on the efficacy of ultrasound-guided fistuloplasty versus fluoroscopy-guided fistuloplasty in patients with dysfunctional arteriovenous fistula

2 Name of investigator and institution:

	Name of Investigator	Institution
a.	Dr Ehab Bin Said	Hospital Kuala Lumpur, Jalan Pahang, 50586 KUALA LUMPUR, Wilayah Persekutuan Kuala Lumpur
b.	Mr Putera Mas Pian	Hospital Kuala Lumpur, Jalan Pahang, 50586 KUALA LUMPUR, Wilayah Persekutuan Kuala Lumpur
c.	Mr Ahmad Rafizi Hariz Bin Ramli	University Malaya Medical Centre, Jalan Profesor Diraja Ungku Aziz, Lembah Pantai, 59100 KUALA LUMPUR

3 Name of sponsor: Self-funded. This research/study is not being funded by any one individual, organization or company.

4 Introduction:

Patients who need haemodialysis often suffer from narrowing of fistulae created for the purpose. There is a study that is being planned by doctors who want to find a safer and better way to repair narrowed fistulae.

You are invited to participate in the study because your fistula is also found to be narrowing.

This document is meant to explain the research mentioned. If you are interested in being a participant in the study, you are urged to read through it for your understanding.

You may ask the doctors who will be performing the study for more information.

Participation in this study is voluntary.

If you participate, you can still withdraw from it any time you want to.

Your entitlement to any medical/health care benefits will remain the same regardless of whether you participate partially, fully or not at all.

If you withdraw, any data collected up till then, will still be used for the study.

You participation begins once you put your signature on the informed consent form at the end of this document.

This study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

A total of 88 subjects like you from Hospital Kuala Lumpur and University Malaya Medical Centre will be participating in this study. The study period is about eighteen months and your participation will be about six months.

5 What is the purpose of the study?

The purpose of this study is to prove that ultrasonic imaging guided fistuloplasty procedure (fistula repair) is at least as efficient as when guided by x-ray imaging.

A successful conclusion of this study shall mean we have moved one step closer towards a better and safer way to repair narrowed fistulae.

Normally, repairing fistula is done using x-ray imaging. Exposure to X-rays however maybe harmful in the long run. In addition, chemicals often injected into the blood to enhance imaging can also harm the patient.

Doctors wish to find a way to minimise patient exposure to X-rays and chemical injections mentioned earlier. Using ultrasound imaging to repair fistulae is one example.

If successful, such repairs can be done without hospital admission which is an added advantage. This will free up much needed hospital beds.

6 What will participants / subjects experience during the course of the study?

You can expect to experience the following:

6.1 Preliminary examinations; the study doctors will need establish and record your medical condition. This they will do through physically examining you as well as talking to you. These examinations include taking radiograms of your fistula, recording your vital signs, blood flow, pressure and heart rate.

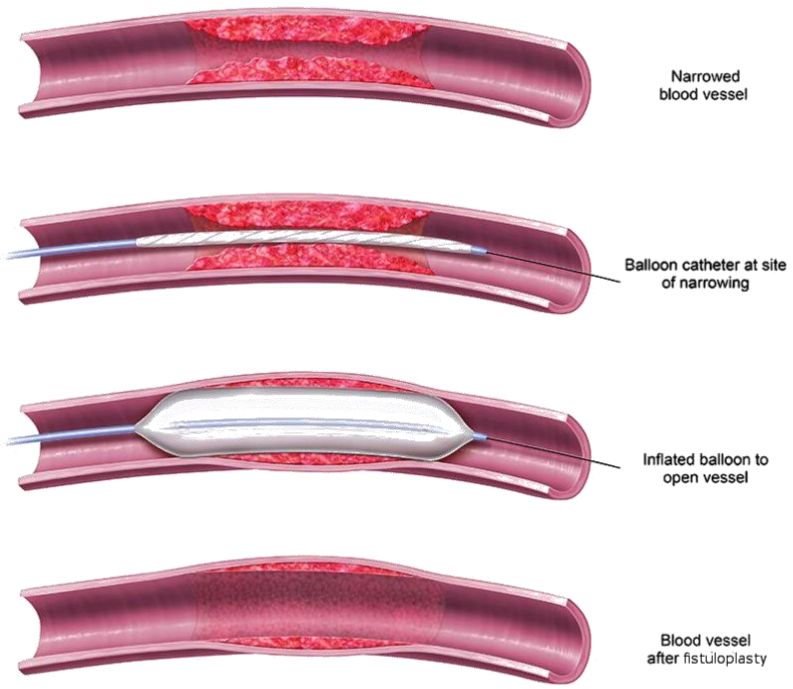
The doctor will also need know your health history. He will do this both by reading your hospital records as well as by asking you specific question. The purpose is to be sure of avoiding subjecting you to unnecessary risks during the course of the study. Specifically in this study the doctor is looking to avoid causing you to bleed uncontrollably. Patients with certain blood disease or those taking blood thinning medication are not suitable candidates for this study.

6.2 You will be assigned to one of the two study groups. The chance of you being placed in either one of the groups is even.

6.3 As mentioned earlier, participants for this study are selected from among those whose fistulae are narrowing i.e. those who will need fistuloplasty procedure (fistula repair, re-widening of narrowed fistula) performed.

The procedure involves inflating a balloon where the fistula is narrowed for a short while. This will be done under local anaesthesia and in sterile conditions.

The pictures below shows how it is done



The procedure is exactly the same for every participant in the study. The only difference being for group 1, the doctor uses ultrasound imaging to see and help him guide the catheter and balloon into place.

For group 2 the doctor does the same with the aid of X-ray imaging.

6.4 After the procedure is completed, the patient will be retained for half a day for observation. He will be examined for any sign of a failed fistuloplasty. In such a case, an appointment will be made for fistuloplasty (via conventional method) for later.

We expect 94% of fistuloplasty done will be successful.

6.5 Study participants/subjects whose fistulae are successfully re-widened will then be requested to be present for follow-up visits at two weeks, one month, three months and six months after fistuloplasty. During these visits, condition of the participants will be assessed along with condition of his fistula. Specifically the following examinations/test/measurements will be conducted:

6.5.1 Examination for symptoms of narrowed fistula (physical and questions)

6.5.2 Blood flow (listen to sound, blood flow meter – strap around arm)

6.5.3 Percentage recoil (width of fistula measurement)
6.5.4 Continuous dilated vein segment (length of dilated fistula measurement)
6.5.5 Reduction of venous dialysis pressure – blood pressure measurement

These follow-up sessions will not be of more than 2 hours duration.

7 Will there be non-halal products used during the research?

No. There will **NOT** be any non-halal items nor any substance derived from animal parts or secretions in the study.

8 Will I receive trial products and how should it be kept?

This study is not meant to test new medicine or chemical product. There will be no oral or injection of new medication or product prescribed for the study.

9 What are the benefits of being in this study?

There is no direct benefit for you. However lessons from this study will help improve treatment and management of patients suffering the same ailment with you included. You will have contributed to this.

10 Assuming I want to be a subject / participant in the study, how do I go about it?

Deciding that you want to be a subject of the study, and being satisfied that you understand what it means, kindly put your signature in the space provided on the consent form (last page of this document).

Then, return the duly signed consent form to the study doctor.

He will then make arrangements to for a preliminary examination as describe in paragraph 6.1

The study doctor will also tell you when your fistuloplasty appointment shall be as well as the follow up appointments once he knows them.

Other than that, you are encouraged to live a life as normal as you can.

During the whole of the study, no hospital stay is prescribed other than the follow up visits for the planned examinations, tests and observations.

11 What are my responsibilities when taking part in this study?

11.1 In a clinical study like this one, accuracy of observation and data is of prime importance. Apart from observations, measurements and tests that doctors make, there are many things that they cannot observe directly.
   a. For this reason, it is important that you answer all questions posed by the doctors and other staff honestly and completely.
   b. If your feel your health and bodily functions in association with certain events of the study, tell the study doctors voluntarily. They may not be aware.

11.2 Subjects in this study are prohibited from taking anti-coagulants due to risks of uncontrolled bleeding. There may be other medications that you are ill advised from taking.
   a. Consult the study doctor before taking any new medication. If another doctor you are seeing makes any change to your current treatments tell him that you are a subject in this study.
   b. Then ask the study doctor for advice.

11.3 If you are suddenly or gradually feeling more ill, tell the study doctor. He may suspend or terminate your participation after investigating. Your continued health is more important that being in a study program.

12 As a former participant, will there be continued health care for my illness?

The care that you were getting for your illness before is already the best that current medical knowledge and expertise has to offer.

Upon completion, you can continue to get the same care.

If the study is successful, the lessons learnt will be used to improve the method of managing narrowed fistula. Here lay the real benefits gained from it.

13 What are the potential risks and side effects of being in this study?

13.1 Everyone who has a narrowing fistula has to undergo fistuloplasty at some point. The risks and side effects are therefore exactly the same for participants and non-participants.

13.2 Risks, side effects and their mitigation are below tabulated. The risks are minor:

	RISK DESCRIPTION	RISK PROBABILITY %	EFFECT	MITIGATION
13.2.1	**Risks During Preliminary Examination to establish Health Condition Baseline**			
a.	Ionizing radiation exposure from fluoroscopic imaging of fistula	minor	minor	Minimize duration and intensity
b.	Exposure to contrast enhancer injection	minor	minor	Selection of subject who are not adverse to the product.
13.2.2	**Fistuloplasty Associated Risks**			
a.	Fistula rupture	3.5	Bleeding	Application of direct pressure
b.	Guide wire false route	0.5	Bleeding	Application of direct pressure
c.	Bleeding at puncture site	0.5	Bleeding	Application of direct pressure
d.	Fistula blockage (failed fistuloplasty)	1	Dialysis treatment difficult	Create new AV fistula
e.	Balloon rupture (failed fistuloplasty)	0.5	Bleeding	Conversion to surgical procedure
13.2.3	**During Follow-up Assessment Examinations**			
a.	Ionizing radiation exposure from fluoroscopic imaging of fistula	minor	minor	Minimize duration and intensity
b.	Exposure to contrast enhancer injection	minor	minor	Selection of subject who are not adverse to the product.
13.2.4	**Fluoroscopy associated risks (for subjects in group 2 and during fistuloplasty)**			
a.	Radiation exposure	minor	minor	Minimize duration and intensity
b.	Exposure to contrast enhancer injection	minor	minor	Selection of subject who are not adverse to the product.

13.3 There is a risk that ultrasound guided fistuloplasty may not be as efficient as fluoroscopy guided fistuloplasty. Evaluating and quantifying this risk is what this study is all about. Our hypothesis is that both these methods are equally efficient.

13.4 For those in group 1, if the doctor encounters difficulty in using ultrasound method to widen your narrowed arteriovenous fistula segment, the doctor may switch to using x-ray fluoroscopy. This is the conventional method. Your risk exposure will then equate to those describe in item 13.2.4 a and 13.2.4 b above

Please ask your study doctor if you need more information on risks and side effects.

14 If I consent to being one of the study subjects, when and how would the consent becomes void?

The consent is valid until such a time when one or more of the following conditions become true:

a. The condition of your health as required by the study criteria is no longer within the acceptable bounds.
b. Procedures and methods to be employed have departed significantly from what is described in this document.
c. Equipment(s) used is/are no longer the same (type/strength etc.) as you have been told.
d. There is new information which signifies that risks to subjects of the study are not the same as earlier informed.

Should any of the above become true, you will be duly informed. You may well decide to reaffirm your consent, re-consent or withdraw from the study. The decision will be yours to make.

15 Will I be paid for participating?

Subjects participation into this study is on voluntary basis. You will not be paid regardless of whether participation is full or partial.

16 What if I am injured during this study?

If you are injured during the study, tell the study doctor. They are anticipating there will be complication in a very small number of cases. Both methods of fistuloplasty are already quite commonly performed and complications are well known and will be managed as part of the patient's treatment. Refer to complications and mitigation steps as earlier described in paragraph 13

Your legal right, to seek compensation will not be diminished in any way by your consenting to participate as a study subject.

17 What are my alternatives if I do not participate in this study?

Standard treatment i.e. fluoroscopy guided fistuloplasty (fistula repair using x-ray imaging) is available. Your entitlement to the best treatment available remains as is.

18 Do the study/research activities add to the cost of my treatment? If yes, who will pay for it?

There is no extra hospital treatment cost / charge for subjects of the study due to study/research activities. Normal cost for fistula repair remains yours to bear.

19 Can the research or my participation be terminated early?

Yes. The study doctor may due to concerns for your safety, stop the study or your participation at any time. If the study is stopped early for any reason you will be informed and arrangements made to ensure you continue to receive proper care.

You will be requested to attend a final follow-up visit.

20 Will my medical information be kept private?

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. In any publication or presentation resulting from it, your identity will be kept secret.

Everyone who can access the records is bound by the same laws of confidentiality.

Data from the study may be archived for the purpose of longer term data keeping and analysis, but your identity will not be revealed at any time.

With your permission your family doctor will be informed of your participation in the study.

21 Who can best answer my questions about anything at all concerning the study/research?

You can call study doctor: Dr Ehab Bin Said at telephone number +60196343874.

If you have any questions about your rights as a participant in this study, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-3362 8407 / 8205 / 8888.

Title of Study: A randomized controlled study on the efficacy of ultrasound-guided fistuloplasty versus fluoroscopy-guided fistuloplasty in patients with dysfunctional arteriovenous fistula

By signing below I confirm the following:

- I have been given oral and written information for the above study and have read and understood the information given.
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary and I can at anytime free withdraw from the study without giving a reason and this will in no way affect my future treatment. I am not taking part in any other research study at this time. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the study doctor's (investigator's) instructions related to my participation in the study.
- I understand that study staff, qualified monitors and auditors, the sponsor or its affiliates, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL
- I will receive a copy of this subject information/informed consent form signed and dated to bring home.
- I agree/disagree* for my family doctor to be informed of my participation in this study. (*delete which is not applicable)

Subject:

Signature: I/C number:

Name: Date:

Investigator conducting informed consent:

Signature: I/C number: 910611-07-5443

Name: Ehab Bin Said
MMC No.: 77178 Date:

Impartial witness: (Required if subject is illiterate and contents of patient information sheet is orally communicated to subject)

Signature: I/C number:

Name: Date: