**Participant information sheet**

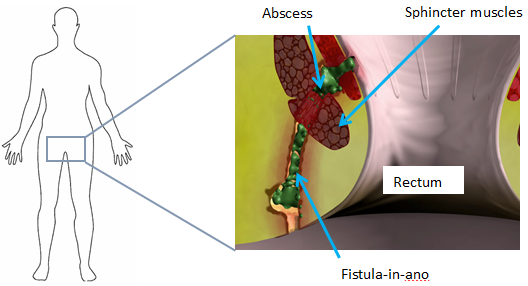
**Seton-Scaffold Clinical Study:**

**Clinical study of the Seton-Scaffold Device for treatment of Fistula-In-Ano (FIA)**

We are a group of researchers based in the University Hospital Birmingham Foundation trust (UHBfT) and University of Birmingham, studying an innovative new device (the Seton-Scaffold) that has been created for the treatment of FIA. This clinical study is part is of a medical device-based research project that is funded by National Institute of Research (NIHR) and sponsored by the device manufacturer, ‘Neotherix Ltd’.

**Why have I been invited?**

You have been invited to take part as you have been diagnosed with a FIA and will soon receive or already have received surgical treatment for your FIA. Before you decide to take part it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information carefully, discuss it with your family, friends, or G.P, if you wish. Please contact us if you would like more information or have any questions. Contact details are listed at the end of this sheet.



**Background**

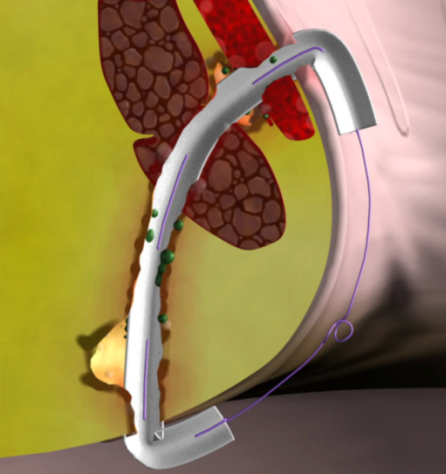
FIA is an abnormal tunnel between the inside of the lower bowel and the skin next to the anus. At least 12,000 people are newly diagnosed with the condition each year in the UK. The FIA condition often starts with an infected gland generating pus, which forms into an abscess and then forms a tunnel when it is draining away.

Shallow fistulas can be cut open so that the tunnel is opened up (‘deroofed’) to form a trench or groove that heals from the bottom of the trench outwards. It will usually take a few weeks for the fistula that has been removed to fill up with scar tissue. The surgery usually requires a general anaesthetic and can be done as a day case procedure.

There are some FIA that are difficult to treat surgically without risking damage to sphincter muscles leading to incontinence. Currently a plastic seton (a long thin piece of plastic intended to sit in the abnormal fistula tunnel long term) is used to keep the tunnel open, allowing the pus to drain away from inside the tunnel as a first step. Sometimes FIA tunnels (also known as fistula tract) can heal after a period of time with a plastic seton. Other times, the patient continues to develop abscesses and the seton cannot be easily removed and the FIA persists.

There are treatments available to attempt to get rid of the tract altogether, but these have a huge variation in success rate and a high risk of the FIA coming back again. Some of these procedures also have a risk of damaging the anal sphincter muscles and can lead to incontinence afterwards. This means that FIA can be a difficult to manage condition and may require multiple operations, clinic appointments and dressing changes.

**What is the Seton-Scaffold device?**

The Seton-Scaffold is a small thin piece of material that has been designed to be placed in the fistula tunnel/tract. It works in much the same way as a plastic seton and drains the pus away. What is unique about the Seton-Scaffold is that it is made of a special scaffold material that encourages direct healing of the fistula. This slowly dissolves away over several months, and any left-over material will simply fall off. The Seton-Scaffold device is made of materials that have been safely used in patients for over 30 years with an excellent safety history.

**What is the Purpose of the study?**

Though there has been a lot of research in this material in healing other wounds, this is the first study testing this device in patients with FIA. Therefore, it is a first in man study. We want to check that the device is safe and understand from a patient’s perspective what it is like to undergo treatment with the new device. The research will be important to identify the areas of the device design that can be improved upon and that is why patients’ thoughts and feedback is critically important.

**What would taking part Involve?**

Participation in this study will mean that you still undergo the same clinic appointments and number of operations as you would have if you would have received regular treatment. However, instead of having a plastic string seton or having one of the many possible FIA treatments, you will have the Seton-Scaffold device placed in theatre under a general anaesthetic. We will then follow your progress over the next 3 months after the procedure.

A member of the research team will speak to you either in person or over a video-call to explain the details of the study and also so that you can ask any questions you may have. If you agree to participate, you will be required to fill in a consent form in clinic or we will send a paper consent to you to be returned after which you will be enrolled in the study.

Before the procedure, you will be asked to fill in a short questionnaire which asks about your quality of life and ability to perform everyday tasks. After the procedure, you will be given a simple diary to be completed weekly after the operation for four weeks and then once every two weeks till week 12. This diary will consist of two questionnaires relating to your pain, comfort level and quality of life. This should not take longer than 5 minutes to complete each time. You can also complete this diary on the phone, with a member of the research team.

If the Seton-Scaffold or your standard seton should fall out before 12 weeks, we will ask you to note down the exact date in your diary. We will also ask you, if possible, to take a picture of the whole or part of device that has fallen off. However, taking a picture is entirely optional.

At 12 weeks, we will ask you to come into for a clinic appointment for a final check of your progress. This will involve examining the fistula wound to see how well it has healed. It will also involve an interview. This appointment is surplus to normal care.

**What is the interview at 12 weeks about?**

This interview will be conducted in a private office with one member of the research team: Dr Elizabeth Li, a surgical doctor. It should last around 30 minutes and will take no longer than 1 hour. If it is not possible to meet in person, we will arrange a video-call to conduct this interview remotely. You can speak freely during this interview and you can bring up and talk about any thoughts you have had about the device and your care pathway that you have received. This information will help us explore your opinion around the device, including any design changes that you think might have made your experience better.

An audio recording will be made of the interview so that the research team do not miss any important points you make. The information you provide and any other individuals you mention will be kept strictly confidential and will have no impact on any subsequent medical care you may receive.

**Expenses**

We will cover the extra travel and parking expenses incurred during your participation in this study. You will not be directly paid for your time for your participation in this study.

**Do I have to take part?**

It is up to you to decide if you would like to join the study. If you agree to take part, we will ask you to sign a consent form which will be done in clinic or posted out to you. You are free to leave the study, without giving a reason at any point.

**What are the risks of taking part?**

1. *Is it riskier than normal treatment?*

The design of the Seton-Scaffold means that it functions as a conventional seton which is to drain infected material away. It will still work in the same fashion as the seton you may have had in normal care.

1. *Are the materials used in the Seton-Scaffold safe?*

There are two components to the Seton-Scaffold:

* The scaffold material is a commonly used substance that has been safely used as medical implants for over 30 years.
* The thread is a suture material that has been in use for over 40 years is used in all surgical specialities.

They both have excellent safety backgrounds. There is the risk that you may have an allergic reaction to the scaffold material or the suture material, however this is very uncommon, and both the scaffold material and suture material normally dissolves away into substances that are naturally produced by your body.

1. *Do I need surgery and to be put to sleep?*

The new Seton-Scaffold does need to be placed in theatre under a general anaesthetic, which is a surgical procedure. However, it is normal to have a small surgical procedure while you are asleep for the treatment for FIA as almost all treatments can be uncomfortable whilst awake. This means that any additional risk above normal care for your FIA is small.

1. *What about the questionnaire and the interview?*

We do not anticipate that there are any risks associated with filling in questionnaires for the study or talking about your experience during an interview. However, sometimes patients may talk about things that are emotional or could be upsetting to them, for example, concerning their experience of living with FIA. Interviews will be conducted in a sensitive manner and you do not have to talk about any issues that you are not comfortable talking about with a researcher.

**What are the benefits of taking part?**

The Seton-Scaffold may deliver healing capabilities above and beyond conventional treatment. It may prevent the need for repeated fistula operations and further procedures that you might have needed if you had conventional treatment. You may find the Seton-Scaffold more comfortable and tolerable than a conventional seton. A small number of other FIA treatments such as an advancement flap and LIFT procedure can affect normal anal sphincter function and risk incontinence. Treatment with the Seton-Scaffold is less invasive and does not affect sphincter muscles function.

We don’t anticipate any direct personal benefits from taking part in an interview at the end of the study, although some patients do find the opportunity to talk about their experiences during an interview to be a positive opportunity.

**What special precautions and warnings are there?**

The Seton-Scaffold is an absorbable implanted medical device. This means that it cannot be removed or reversed if you decide you no longer wish to participate in the study.

**If you have any urgent issues, please contact:**

**Dr Elizabeth Li (available 24 hour a day, 7 days a week)**

**Mobile: 07568306996**

Allergies:

If you have a known allergy to poly-L lactic acid or polyglactin 910 (commonly known as Vicryl), you would not be able to receive fistula treatment using the Seton-Scaffold device. Rarely, it can cause severe allergic reactions up to a week after initial treatment. If this occurs or you are experiencing other unusual reaction, please contact the research team (details at the end of this document).

Other reactions:

Poly-L lactic acid can cause local irritation or local inflammation. If you are experiencing increased pus discharge, increased pain, have signs of infection, or you are experiencing another unusual reactions please contact the research team (details at the end of this document).

Pregnancy and breast feeding:

Though the materials in the Seton-Scaffold have been used in implants for over 30 years, it is unknown if poly-L lactic acid is safe for use during pregnancy and it is unknown if poly-L lactic acid passes through breast milk. Therefore if you are pregnant or breast feeding or are thinking about becoming pregnant or breast feed, you would not be able to receive FIA treatment using the new device. You are still able to participate in the questionnaire part of the study, if you so wish.

CT scans and MRI scans:

It is unknown if poly-L lactic acid will show up on an MRI or CT scan. If you need an MRI or CT scan, make sure to warn your healthcare provider that you have received an implant of this product, in case it does show up on the scan.

**What information will be collected from me?**

If you take part in this study the research team will need to know your name and contact details so they can contact you about your research appointments, or to send you questionnaires. Researchers must always make sure that as few people as possible can see this sort of information that can show who you are. In this study, most of the research team will not need to know your name. Someone will remove your name from the research data and replace it with a research identifying number. This is called coded data, or the technical term is pseudonymised data.

We will need to use information from you and your medical records for this research project.  University Hospital Birmingham will use the following information, which will include your:

* Name
* Contact details (your contact number, and home and email addresses)
* NHS number

The sponsor will use the following information for the purposes of research:

* Your research identifying number
* Your medical records relating to FIA disease. This will include the history of your illness and symptoms, the type and severity of the FIA, the type treatments and number of operations you may have had already, the medications that you needed and the results of any scans.
* The data generated from this research project. This will include what we will ask about your pain, comfort and quality of life in the form of a diary after your treatment
* The qualitative interview will delve deeper into your feedback and thoughts around the Seton-Scaffold device and your treatment overall. You can speak your thoughts freely here about aspects such as in insertion of the device, how comfortable it is, how hygienic you find it, how it has affected your social life (if at all) and your ability to work. You do not have to discuss anything you do not wish to or find uncomfortable.

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a research identifying number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

The research generated from your data will answer questions related to the Seton-Scaffold in treating FIA disease. This information will help support good quality research data, policy making and other decision-making in the future. The research data maybe shared via publications and conference presentations with the wider international scientific community in the future. Your personal and medical data will always remain fully anonymised.

We may use anonymised quotations in publications and presentations, but we will do so in a way that means that you cannot be identified.

**Will my taking part in the study be kept confidential?**

UHBft will keep your name, NHS number and contact details confidential and will not pass this information to Neotherix Ltd. UHBfT will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Neotherix and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Neotherix will only receive information without any identifying information.

All the research data gathered from this study will be confidential and kept by the research team based in the University Hospitals Birmingham. Your data will be entered onto a secure database, hosted by locally the University Hospitals Birmingham. Your data will only be accessed by responsible persons directly part of the research team for the purpose of medical research only, as per the Caldicott Principles. Participation in the study will have no effect on your clinical care outside of the Seton-Scaffold treatment, unless a clinical issue was to come to light which could cause direct and/or ongoing harm to yourself.

With your permission, your GP doctor will also be informed of your participation in this study.

UhBfT will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that UHBfT are responsible for looking after your information and using it properly. UHBfT will keep identifiable information about you for 10 years after the study has finished.

**What are your choices about how your information is used?**

* You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
* If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop.
* We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.
* To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at:

[www.research.uhb.nhs.uk/legal-information/privacy-policy](http://www.research.uhb.nhs.uk/legal-information/privacy-policy).

* You can also access further information from: [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)

**Patient and Public Involvement**

Patient representatives have been involved in the design of not only the device itself, but the set-up of this study from the very beginning of this project. They have provided a voice from a patients’ point of view to guide the research and speak on behalf of FIA patients. The documentation related to the study, the study design and the device have all undergone the approval of the FIA patient representatives.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to a member of the research team who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting UHB’s Patient Advice and Liaison Service (PALS) via one of the following methods:

* drop at the PALS office, located on Level 0 of QEHB (opposite the Outpatient Pharmacy)
* complete their online form by visiting https://www.uhb.nhs.uk/pals-contact.htm
* e-mail at PALS@uhb.nhs.uk
* call on 0121 371 4400

**Further information**

This study is led by Miss Elizabeth Li (Surgical Registrar and Clinical Research Fellow) and supported by Professor Thomas Pinkney, Professor of Clinical Trials and Consultant Colorectal Surgeon as part of the Colorectal Research Group within the University Hospital Birmingham with association with the University of Birmingham and sponsored by Neotherix Ltd. This study funded by the National Institute of Health Research Invention for Innovation Scheme.

**The London-Stanmore Research Ethics Committee has approved the ethics of the study.**

**Contact:**

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