

# Frequent, far infra-red (FIR) therapy for newly formed arterio-venous fistulas in dialysis and pre-dialysis patients

<b>Submission date</b> 03/05/2013	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 03/05/2013	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 25/07/2017	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Haemodialysis (HD) removes poisons from a patient's bloodstream when their kidneys no longer work. The best way of getting access to blood is through a permanent fistula, formed by surgically connecting a patient's artery and vein. Poor access is a major cause of ill health in HD patients so a well-functioning fistula is very important. Over the course of a few weeks, a newly formed fistula should strengthen enough to be able to be used for dialysis. Unfortunately, this does not always occur and this can cause problems with providing high-quality dialysis treatment. In addition, further operations may be required and there is the risk that dialysis treatment will need to be given through a dialysis catheter (a plastic tube that is inserted into one of the veins in the neck). These catheters carry a higher risk of infection. Anything that improves the chances that a fistula will be strong enough for dialysis is therefore important. A treatment called Far Infra Red (FIR) therapy has been shown to preserve the health of fistulas in patients already using them for HD. FIR therapy lamps emit a non-visible light and have a long history of use in different medical conditions and for sports injuries. FIR therapy seems to work by improving the function of blood vessels. The purpose of this study is to test whether FIR therapy might help strengthen newly-formed fistulas.

### Who can participate?

The study is open to patients waiting to have a fistula formed and who are either already receiving dialysis or who have not yet started dialysis (i.e. they are pre-dialysis). They should be at least 18 years old, they should not have a reduced conscious level at the time of their first FIR therapy and should not have reduced peripheral sensation.

### What does the study involve?

Participants in the study will be randomly allocated to either continue usual care (the control group) or to receive FIR therapy, using a FIR lamp, five times a week, at home for 6 weeks after surgery. Pre-dialysis patients will conduct all their treatments at home. Similarly, patients waiting to transfer from peritoneal dialysis to haemodialysis will conduct all their treatments at home. Patients already receiving haemodialysis will have treatment provided when they are on the dialysis machine. The remaining FIR treatments will, however, need to be performed at

home, in between dialysis sessions. The development of fistulas in the two groups will be compared using ultrasound scanning, 6 and 12 weeks after surgery.

What are the possible benefits and risks of participating?

Improving the development of fistulas would be very desirable because of the problems HD patients suffer with poor fistulas. It is not yet clear whether FIR therapy will, in fact, improve the development of fistulas, which is why this study is being conducted. Provided the FIR lamp is used at the correct distance from the patient's arm, all that they should feel will be a sensation of warmth. This should not be uncomfortable but if it does become so, they should stop treatment - skin damage is very unlikely if this is done. As an extra precaution, we will ask the participant to examine their skin over their fistula after each FIR lamp treatment for redness. If this occurs, we will ask that they let us know and we will advise them to stop further treatment whilst this is being evaluated. FIR therapy requires the participant's co-operation in keeping their arm under the lamp for 40 minutes and also in removing it, if it ever becomes uncomfortable. Patients will not receive FIR therapy if they are unable to co-operate with treatment for instance, if they lose consciousness or the ability to make decisions for themselves. FIR therapy is widely used across dialysis units in Taiwan without any reports of harm to patients. FIR lamps are also in widespread use in gyms and spas around the world.

Where is the study run from?

The study will be run from Renal Services centre at the Freeman Hospital, Newcastle upon Tyne, UK.

When is the study starting and how long is it expected to run for?

The study will run from 1st July 2013 to 31st October 2017.

Who is funding the study?

The study has been funded by Stanningley Pharma (UK) and by the Northern Counties Kidney Research Fund (UK).

Who is the main contact?

Dr N.S. Kanagasundaram  
suren.kanagasundaram@nuth.nhs.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr N S Kanagasundaram

### Contact details

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Newcastle upon Tyne  
United Kingdom  
NE7 7DN

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suren.kanagasundaram@nuth.nhs.uk

# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

14042

## Study information

### Scientific Title

Frequent, far infra-red (FIR) therapy for newly formed arterio-venous fistulas in dialysis and pre-dialysis patients

### Study objectives

Current hypothesis as of 15/09/2014:

Haemodialysis (HD) removes poisons from a patient's bloodstream when their kidneys no longer work. The best way of getting 'access' to blood is through a permanent fistula, formed by surgically connecting a patient's artery and vein.

Poor 'access' is a major cause of ill health in HD patients so a well functioning fistula is very important. A treatment called Far Infra Red (FIR) therapy has been shown to preserve the health of fistulas in patients already using them for HD. Our study aims to see whether FIR can also help the development of newly-formed fistulas in the 6 weeks after they have been created. Participants in the study will be randomised to either continue usual care (the control group) or to receive FIR therapy, using a FIR lamp, 5 times a week, at home for 6 weeks after surgery. The development of fistulas in the two groups will be compared using ultrasound scanning, 6 and 12 weeks after surgery.

Previous hypothesis:

Haemodialysis (HD) removes poisons from a patient's blood stream when their kidneys no longer work. The best way of getting 'access' to blood is through a permanent fistula, formed by surgically connecting a patient's artery and vein.

Poor 'access' is a major cause of ill health in HD patients so a well functioning fistula is very important. A treatment called Far Infra Red (FIR) therapy has been shown to preserve the health of fistulas in patients already using them for HD. Our study aims to see whether FIR can also help the development of fistulas before they are needed for dialysis, in the 6 weeks after they have been created. Participants in the study will be randomised to either continue usual care (the control group) or to receive FIR therapy, using a FIR lamp, 5 times a week, at home for 6 weeks after surgery. The development of fistulas in the two groups will be compared using ultrasound scanning, 6 and 12 weeks after surgery.

More details can be found at:<http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=14042>

On 15/09/2014 the following changes were made to the trial record:

1. The public title was changed from 'Home Far Infra-red (FIR) therapy for Arterio-venous Fistulas (AVFs)' to 'Frequent, far infra-red (FIR) therapy for newly formed arterio-venous fistulas

in dialysis and pre-dialysis patients.'

2. The scientific title was changed from 'Home Far Infra-red (FIR) Therapy for newly formed Arterio-venous Fistulas in pre-dialysis patients' to 'Frequent, far infra-red (FIR) therapy for newly formed arterio-venous fistulas in dialysis and pre-dialysis patients.'

3. The anticipated end date was changed from 30/04/2015 to 31/10/2017.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

NRES Committee North East - Newcastle and North Tyneside 2, favourable opinion given 22/05/2013, REC ref: 13/NE/0054; favourable opinion on substantial amendment (to broaden participation) given 11/09/2014

## **Study design**

Randomised interventional treatment trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

## **Health condition(s) or problem(s) studied**

Topic: Renal and Urogenital; Subtopic: Renal and Urogenital (all Subtopics); Disease: Renal

## **Interventions**

Current interventions as of 15/09/2014:

Pre-dialysis or dialysis patients awaiting AV fistula formation and randomised on a 1:1 basis between treatment and control groups.

Far infrared (FIR) therapy, 40-minute FIR therapy sessions, administered using a FIR lamp, five times a week for 6 weeks after AV fistula surgery.

Follow-up length: 3 months

Study entry: single randomisation only

Previous interventions:

Pre-dialysis patients awaiting AV fistula formation and randomised on a 1:1 basis between treatment and control groups.

Far infrared (FIR) therapy, 40-minute FIR therapy sessions, administered using a FIR lamp, five times a week for 6 weeks after AV fistula surgery.

Follow-up length: 3 months

Study entry: single randomisation only

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Access flow at 6 weeks measured by ultrasound

### **Secondary outcome measures**

Access flow at 12 weeks after AV fistula formation measured by ultrasound

### **Overall study start date**

01/05/2013

### **Completion date**

31/10/2017

### **Reason abandoned (if study stopped)**

Participant recruitment issue

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 15/09/2014:

1. Pre-dialysis or dialysis patients undergoing formation of a brachial arterio-venous fistula
2. Ability to provide informed consent
3. Male and female, age  $\geq$  18 years

Previous inclusion criteria:

1. Pre-dialysis patients undergoing formation of a brachial arterio-venous fistula
2. Ability to provide informed consent
3. Male and female, age  $\geq$  18 years

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

**Target number of participants**

UK Sample Size: 72

**Key exclusion criteria**

1. Impaired conscious level at the time of 1st FIR therapy
2. Impaired peripheral sensation

**Date of first enrolment**

01/05/2013

**Date of final enrolment**

31/10/2017

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Freeman Road**

Newcastle upon Tyne

United Kingdom

NE7 7DN

## **Sponsor information**

**Organisation**

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

**Sponsor details**

Leazes Wing, Royal Victoria Infirmary

Queen Victoria Road

Newcastle Upon Tyne

England

United Kingdom

NE1 4LP

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.newcastle-hospitals.org.uk/>

**ROR**

<https://ror.org/05p40t847>

## Funder(s)

### Funder type

Charity

### Funder Name

Northern Counties Kidney Research Fund (UK)

### Alternative Name(s)

NCKRF

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

### Location

United Kingdom

### Funder Name

Stanningley Pharma Ltd (UK)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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