ISRCTN07415424 https://doi.org/10.1186/ISRCTN07415424

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

Submission date
03/05/2013

Recruitment status
Stopped

Registration date
03/05/2013

Overall study status
Stopped

Last Edited
25/07/2017

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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?
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Contact information

Type(s)
Scientific

Contact name
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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 >= 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 >= 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?

HRA research summary	28/06/2023	No	No