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The study of the effect of far infrared therapy on the inflammatory markers and the haemodynamic parameters of vascular access in patients with end stage renal disease

Submission date 20/11/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 21/02/2008	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/08/2011	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NSC-96-2314-B-010-045

Study information

Scientific Title

Study objectives
Please note that as of 03/03/2008 this trial record was extensively amended. Most of the changes to this record can be found in the relevant field, under the date on which the amendment was made. The following changes have also taken place:
1. At the time of amendment, the above title was changed from 'The study of the effect of far infrared therapy on the inflammatory markers and the haemodynamic parameters of vascular access in haemodialysis patients' to the above title
2. The anticipated end date of this trial was extended to 09/10/2008; the previous anticipated end date was 19/10/2007
3. The number of participants has been increased to 200 in total; the previous number of participants was 20

Current hypothesis as of 03/03/2008:
In this study, we evaluated whether there is an interaction between far infrared radiation (FIR) and heme oxygenase-1 (HO-1) in regulating vascular inflammation. FIR therapy may exert an anti-inflammatory effect via the induction of HO-1. The potential effect of FIR therapy to inhibit inflammation may play a critical role in preserving blood flow and patency of arteriovenous fistulas (AVFs) in patients with end stage renal disease (ESRD).

Previous hypothesis:
In this study, we evaluated whether there is an interaction between far infrared radiation (FIR) and heme oxygenase-1 (HO-1) in regulating vascular inflammation. FIR therapy may exert an anti-inflammatory effect via the induction of HO-1. The potential effect of FIR therapy to inhibit inflammation may play a critical role in preserving blood flow and patency of arteriovenous fistulas (AVFs) in haemodialysis patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Institutional Review Board (IRB) of Taipei Veterans General Hospital on the 19th November 2007 (ref: 96-10-11A).

Study design
Randomised, controllled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Stenosis of arteriovenous fistula

Interventions
Current interventions as of 03/03/2008:
HD patients:
40 minutes of far-infrared therapy during the second and the subsequent sessions of haemodialysis three times a week (TIW) for a duration of one year.

Non-HD ESRD patients:
40 minutes of far-infrared therapy three times a week (TIW) for a duration of three months.

Previous interventions:
One session of 40 minutes of far-infrared therapy during the second session of haemodialysis.

Blood samples were analysed for serum:
1. Soluble intercellular adhesion molecule-1 (ICAM-1) and vascular cell adhesion molecule-1 (VCAM-1)
2. High sensitivity C-reactive protein (hsCRP)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Current primary outcome measure as of 03/03/2008:
Unassisted patency of vascular access.

Previous primary outcome measures:
1. Soluble ICAM-1 and VCAM-1 by specific enzyme-linked immunosorbent assay (ELISA) (Diaclone, Besançon, France)
2. High sensitivity C-reactive protein (hsCRP)

Blood samples will be collected every three months for a study period of one year.

Secondary outcome measures
Current secondary outcome measure as of 03/03/2008:
1. Blood samples were analysed for the following items every three months:
1.1. Soluble intercellular adhesion molecule-1 (ICAM-1) and vascular cell adhesion molecule-1 (VCAM-1)
1.2. High sensitivity C-reactive protein (hsCRP)
2. Haemodynamic parameters (access flow, cardiac output and total peripheral resistance) will be measured by HD-02 monitor every three months in HD patients and by Doppler ultrasonography in non-HD ESRD patients

Previous secondary outcome measure:
Access blood flow; blood samples will be collected every three months for a study period of one year.

Overall study start date
08/10/2007

Completion date
09/10/2008

Eligibility

Key inclusion criteria
Current inclusion criteria as of 03/03/2008:
HD Patients:
1. Are receiving four hours of maintenance haemodialysis (HD) therapy three times weekly for at least six months
2. Are using a AVF or AV graft as the present vascular access for more than six months, without interventions within the previous three months

Both HD and non-HD ESRD patients:
1. Are without fever or clinical signs of active infection
2. Creation of AVF with the standardised surgical procedures of venous end-to-arterial side anastomosis or AV graft with loop conformation by cardiovascular surgeons in our hospital in the upper extremity
3. Are between 20 and 80 years of age, both genders

Previous inclusion criteria:
Patients:
1. Are receiving 4 hours of maintenance haemodialysis (HD) therapy three times weekly for at least six months
2. Are using a native AVF as the present vascular access for more than six months, without interventions within the last three months
3. Are without fever or clinical signs of active infection
4. Creation of AVF by cardiovascular surgeons in our hospital with the standardised surgical procedures of venous end-to-arterial side anastomosis in the upper extremity
5. Are between 20 and 80 years of age, both genders

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100 HD patients (50 on FIR and 50 controls) and 100 non-HD ESRD patients (50 on FIR and 50 controls).

Key exclusion criteria
Current exclusion criteria as of 03/03/2008:
Patients use Perm catheter as vascular access for haemodialysis.

Previous exclusion criteria:
Patients use AV graft or Perm catheter as vascular access for haemodialysis.

Date of first enrolment
08/10/2007

Date of final enrolment
09/10/2008

Locations

Countries of recruitment
China

Taiwan

Study participating centre
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Sponsor information

Organisation
National Science Council (Taiwan)

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Sponsor type
Government

Website
http://web.nsc.gov.tw/

ROR

https://ror.org/02kv4zf79

Funder(s)

Funder type
Government

Funder Name
National Science Council (Taiwan)

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