ISRCTN82322174 https://doi.org/10.1186/ISRCTN82322174

Assessment of the sympathetic nervous system blockade of the upper limb after a brachial plexus block in patients receiving haemodialysis

Submission date 08/02/2010	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/02/2010	**Overall study status** Stopped	
Last Edited 05/03/2013	**Condition category** Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Iain Moppett

Contact details
University Department of Anaesthesia
Queen's Medical Centre
Nottingham
United Kingdom
NG7 1AA
+44 (0)115 924 9924 ext. 31003
iain.moppett@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
07AN007

Study information

Scientific Title
Assessment of the sympathetic nervous system blockade of the upper limb after a brachial plexus block in patients receiving haemodialysis: an observational single centre cohort study

Study objectives
Regional anaesthesia of the upper limb results in blockade of motor and sensory nerves, providing surgical and post-operative analgesia. Sympathetic nerves are also blocked resulting in local vasodilatation. This may be of benefit in surgery where enhanced blood flow is beneficial such as arterio-venous fistula creation. The degree and duration of sympathetic blockade produced by regional blocks however, has never been quantified. This study aims to quantify sympathetic blockade by measuring the changes in skin blood flow and skin temperature after placement of a brachial plexus block.

Laser Doppler flowmetry is a non-invasive technique for estimating blood flow flux. Briefly, it consists of applying a small probe to the surface of the forearm. This probe is connected by a fibreoptic cable to a small, weak laser. Visible laser light is shone at the skin. Some of this light is reflected back and picked up by a light detector that is also part of the probe. Some of this reflected light would have had its frequency changed because of the Doppler effect when it hits moving red cells. The path of the light back to the probe is not direct, but affected by scattering, thus the probe can say nothing about direction of flow, just that it is happening. The overall change in frequency seen is proportional to the blood flow flux: a vectorless unit of flow velocity. By plotting the output from the Doppler probe against time, changes in blood flow flux in response to stimuli can be observed.

The transient hyperaemic response is a test of dynamic vascular function that has been extensively studied in our department and elsewhere. Most vascular beds autoregulate to some extent. That is they maintain blood flow in the face of varying perfusion pressures. They achieve this by dynamically changing the resistance of the vascular bed when perfusing pressure changes. These changes are rapid, but not instantaneous, so if perfusion pressure is dropped briefly (e.g. by feeding artery occlusion) and then released, there will be an overshoot of flow just after the compression is released. This is known as the transient hyperaemic response (THR).

Laser Doppler flowmetry and THR has previously been used to study vascular reactivity in the upper limb and is a safe and reproducible measure of changes in skin blood flow flux. The THR response has been shown to be abolished when skin vessels are maximally dilated by local application of a known vasodilator (sodium nitroprusside). A number of studies in our department have shown the THR test to be a reproducible indicator of vascular reactivity that can reliably be used for comparing repeated measurements in individuals. Therefore, the test is an attractive tool for studying the effects of sympathetic blockade on skin vascular reactivity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Derbyshire Research Ethics Committee approved on the 12th October 2007 (ref: 07/H0401/129). Amendment 1 approved on the 20th January 2010.

Study design

Single centre observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Renal failure

Interventions
Subjects will have a measure of their forearm blood flow made on three occasions:
1. Immediately before the insertion of the regional block for surgery
2. Immediately after the insertion of the regional block for surgery
3. Four hours post-insertion of regional block

Subjects will be asked to refrain from exercise and eating or drinking caffeine-containing substances for 2 hours prior to the measurement of blood flow. They will spend at least 15 minutes acclimatising to the environment prior to starting the experiment.

For the measurements to be made four hours after surgery:
Subjects will sit semi-recumbent with the arm to be measured outstretched. The laser Doppler flowmeter probe will be attached to both forearms using a specially designed adhesive chamber and a temperature probe applied to the skin adjacent to the flowmeter. Output from the flowmeter will be recorded on a laptop computer. The skin blood flow flux and temperature will monitored until a steady baseline is reached.

The position of the axillary artery will then be identified by palpation. The axillary artery will then be compressed for a period of 20 seconds aiming for complete occlusion (as assessed by 'zero' flux on the recording computer). The pressure will then be released and the hyperaemic response recorded. This will be repeated three times at 2-minute intervals to allow mean values to be calculated.

For measurements to be made pre- and post-regional block:
Subjects will lie down with the arm to be measured outstretched. The laser Doppler flowmeter probe will be attached to both forearms using a specially designed adhesive chamber and a temperature probe applied to the skin adjacent to the flowmeter. Output from the flowmeter will be recorded on a laptop computer. The skin blood flow flux and temperature will be recorded on the recording computer until a steady baseline is reached.

The position of the axillary artery will then be identified by palpation. The axillary artery will then be compressed for a period of 20 seconds aiming for complete occlusion (as assessed by 'zero' flux on the recording computer). The pressure will then be released and the hyperaemic response recorded. This will be repeated three times at 2-minute intervals to allow mean values to be calculated.

The regional block will then be performed by the anaesthetist responsible for that operating list. The block will be via the axillary, supraclavicular or interscalene approach as is deemed most appropriate by the anaesthetist. The blocks will be performed under ultrasound guidance with a peripheral nerve stimulator.

The output from the flowmeter will then be continuously monitored. The onset of the regional block will be assessed at 5 minute intervals, by assessment of cold (using ethyl chloride) and motor power in the hand. The transient hyperaemic response test will then be repeated three times at two minutely intervals. After that, one of the measuring probes will be heated to 44°C and the change in blood flow monitored.

Four hours after the block has been sited, the laser Doppler probe will be reattached, and the blood flow and temperature recorded. The transient hyperaemic response test will then be repeated four times at two minutely intervals. The study is then complete.

05/03/2013: Please note that this trial never started due to a lack of participants.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The transient hyperaemic response ratio (THRR) will be calculated for each compression using the formula THRR = F2/F1 where F1 is the initial fall in blood flow flux following compression of the brachial artery and F2 is the hyperaemic response following its release. The mean of each set of readings will be taken and compared with the subjects' normal values using a paired t-test.
2. Skin temperature will be compared before and after the regional block and dialysis using a t-test

Measured at pre-regional block, immediately post-regional block onset, and 4 hours after regional block.

Secondary outcome measures
No secondary outcome measures

Overall study start date
10/02/2010

Completion date
31/05/2010

Reason abandoned (if study stopped)
Participant recruitment issues

Eligibility

Key inclusion criteria
1. Patients with end stage renal failure
2. Over 18 years of age, either sex
3. Written consent obtained
4. Due to undergo surgery for forearm fistula creation under a regional block

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
30

Key exclusion criteria
1. Smokers
2. Damaged skin on the arm
3. Circulatory disorders such as Raynaud's disease, systemic sclerosis, sickle cell trait or disease
4. Current use of beta blockers
5. Undergoing haemodialysis for more than 12 months

Date of first enrolment
10/02/2010

Date of final enrolment
31/05/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Department of Anaesthesia
Nottingham
United Kingdom
NG7 1AA

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust (UK)

Sponsor details
Research and Development
E11 Curie Court
Queen's Medical Centre Campus
Derby Road
Nottingham
England
United Kingdom
NG7 1AA
+44 (0)115 9709 9049
maria.koufali@nuh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nuh.nhs.uk/

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
Special trustees of Nottingham University Hospitals (UK) - purchased Laser Flowmetry

Funder Name
Nottingham Regional Anaesthesia (UK) - cover running costs

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