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Cerebral venous drainage in multiple sclerosis

Submission date
17/10/2011

Recruitment status
No longer recruiting

Registration date
14/11/2011

Overall study status
Completed

Last Edited
27/04/2018

Condition category
Nervous System 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
Multiple sclerosis is a disease of unknown origin causing disability in young adults. Recently differences in the blood flow in the neck veins have been described in multiple sclerosis. These can be found using a simple ultrasound scan that is safe and acceptable to most patients. The aims of this study are: to establish how common these findings are in a sample of UK multiple sclerosis patients; to establish if these findings are more common in multiple sclerosis patients than people without multiple sclerosis (called controls); to establish how variable ultrasound is in identifying these findings.

Who can participate?
30 patients of any gender over 18 years of age with any pattern of multiple sclerosis with an estimated disease severity score (EDSS) of 6 or less. 30 healthy controls with the same age and gender will also be tested.

What does the study involve?
The study will involve an initial examination by a neurologist to ensure that individuals are suitable to participate. There will then be a one hour ultrasound examination of the neck veins sitting and lying flat. This will be repeated after thirty minutes by a second sonographer.
All participants will be invited back for a second scan by one of the same sonographers.

What are the possible benefits and risks of participating?
Participants will not gain any direct benefit from participating. There are no side-effects.

Where is the study run from?
Imperial College London (UK).

When is the study starting and how long is it expected to run for?
The study will commence in November 2011 and recruit for 1 year, with results expected in early 2013.

Who is funding the study?
Royal College of Surgeons of England, the Circulation Foundation and the Venous Forum at the Royal Society of Medicine (UK).

Who is the main contact?
Dr Richard Nicholas
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Contact information

Type(s)
Scientific

Contact name
Dr Richard Nicholas

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11/LO/1139

Study information

Scientific Title
Cerebral venous drainage in multiple sclerosis: protocol for a blinded, age-sex matched cross-sectional ultrasound study

Study objectives
There will be statistically and clinically significant differences in cerebral venous outflow disturbance between multiple sclerosis patients and healthy controls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
UK National Research Ethics Board, 15/08/2011, ref: 11/LO/1139

Study design
Sonographer blinded age-sex healthy control matched cross-sectional ultrasound study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
All participants will undergo a lying and standing blood pressure measurement and an electrocardiogram (heart tracing) on entry to the study.

All participants will then undergo a one hour ultrasound examination of the neck, comprising thirty minutes lying flat and thirty minutes sitting upright.

At the end of the examination the images will be stored for future analysis at a another time point, i.e. results will not be disclosed to the participant.

Any willing participants will be invited back for a future rescan in 2 weeks by one of the same sonographers. No further follow up is required for this study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Reflux (>0.88s) in the internal jugular (IJV) and vertebral veins (VVs) using triplex mode
2. High resolution B-mode evidence of IJV stenosis in transverse orientation (>50% cross-sectional area diameter reduction) with and without Valsalva
3. Undetectable Doppler flow in the IJVs and VVs using colour and Spectral Doppler
4. Cross-sectional area change of the IJV from the supine to sitting position

Secondary outcome measures
Inter and intra sonographer reproducibility

Overall study start date
01/11/2011

Completion date
01/11/2012

Eligibility

Key inclusion criteria
1. 18 years of age or greater
2. Informed consent
3. Cases: multiple sclerosis by McDonald criteria with estimated disease severity score < 6, any disease pattern
4. Controls: no other relevant health condition
5. Ability to perform Valsalva manoeuvre
6. Stable disease for one month pre-recruitment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Concurrent enrolment in multiple sclerosis drug trial
2. Concurrent masking neurological disease
3. Pregnancy
4. Inability to lie supine
5. Intercurrent infection
6. Superior vena cava obstruction
7. Tricuspid regurgitation
8. Right heart failure
9. Vasculitis
10. Treatment with venodilators (e.g. nitrates)
11. Head and neck surgery or radiotherapy
12. Previous central venous catheterisation
13. Previous central venous thrombosis
14. Thrombophilia
15. Arrhythmia on baseline electrocardiogram (ECG)
16. Postural systolic drop of >30mmHg on standing
17. Steroid treatment within one month
18. Pulmonary hypertension
19. Malignancy

Date of first enrolment
01/11/2011

Date of final enrolment
01/11/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Charing Cross Hospital
MS Day Unit
4 North
London
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W6 8RF

Sponsor information

Organisation
Imperial College London

Sponsor details
Joint Research Office
Exhibition Road
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SW7 2AZ

Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type

University/education

Funder Name
The Royal College of Surgeons of England

Funder Name
The Venous Forum at the Royal Society of Medicine

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