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Change in neck vein flow after chronic cerebro-spinal venous insufficiency (CCSVI) therapy in patients with multiple sclerosis

Submission date	Recruitment status	[ ] Prospectively registered
31/03/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/06/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/06/2011	Nervous System Diseases	[ ] 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
N/A

Study information

Scientific Title
Pulsed short magnetic resonance imaging (MRI) to quantify neck vascular flow changes after jugular venous dilation (venoplasty) in patients with multiple sclerosis

Study objectives
Venous narrowing and thus reduction in jugular vein flow has recently been implicated as a potential contributing factor in Multiple Sclerosis. Jugular venoplasty has been hypothesised to improve jugular venous drainage, and thus improve the symptoms of patients suffering with multiple sclerosis. Many patients have had magnetic resonance imaging (MRI) examinations assessing neck vein and arterial blood flow prior to venoplasty. The aim of this observational study is to use MRI scans to compare the the change in the blood flow in the neck vessels of patients after jugular veinoplasty with their pre-procedural flow measurements

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration - IRB Services approval pending as of 31/03/2011

Study design
Single centre observational longitudinal case control study

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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
Multple sclerosis/ diagnostic imaging

Interventions
Observations:
1. MRI flow quantification will be used to measure blood flow rate averaged over 2 minutes within the right and left internal jugular veins
2. At the same level within the upper neck, left and right arterial blood flow will be measured

3. A ratio of total jugular vein to arterial blood flow will be calculated, and compared to the same measurements and site obtained on pre-procedural MRI scans
4. The change in percentage blood flow will be statistically analysed using the paired t-test

Patients will be provided with a questionnaire form to assess for quality of life changes at the time of the study. This questionnaire includes the following questions:
1. Date and location of CCSVI treatment (venoplasty)
2. Age of diagnosed MS
3. Age of suspected onset, type of MS, current medication, iron chelation or naturopathic treatments, vitamin D supplements
4. Effects pre and post therapy:
4.1. Cold extremities (pre/post)
4.2. Brain fog (pre/post)
4.3. Head fullness (pre/post)
4.4. Fatiguability (hrs of productivity) (pre/post)
4.5. Exercise tolerance (pre/post)
4.6. Colorperception/vision change (post)
4.7. Taste/smell change (post)
4.8. Hearing change (post)
4.9. Temperature tolerance (pre/post)
4.10. Bowel/bladder incontinence change (pre/post)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Paired t-test statistical analysis will be used to assess for significance

Secondary outcome measures
Questionnaire answers will be tabulated to assess for change

Overall study start date
01/04/2011

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. Above 19 years of age
2. Has been diagnosed with multiple sclerosis
3. Has an MRI of the neck veins with flow quantification prior to having jugular venoplasty (CCSVI treatment) within the past 1 year

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Pilot study of 25-50 participants

Key exclusion criteria
1. Patients who have a contraindication to MRI scan
2. Patients with metal implants such as:
2.1. In the eye
2.2. Non-MRI compatible stents
2.3. Staples

Date of first enrolment
01/04/2011

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
Canada

Study participating centre
1371 West Broadway
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Sponsor information

Organisation
AIM Medical Imaging (Canada)

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Sponsor type
Hospital/treatment centre

Website
http://www.aimmedicalimaging.com

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
AIM Medical Imaging (Canada)

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