

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

Submission date 31/03/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/06/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/06/2011	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 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

Multiple 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. Color perception/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

Vancouver

Canada

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Sponsor information**Organisation**

AIM Medical Imaging (Canada)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

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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