

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

Submission date 31/03/2011	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 10/06/2011	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 10/06/2011	Condition category Nervous System Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Raj Attariwala

Contact details
1371 West Broadway
Vancouver
Canada
V6H 1G9
+1 604 733 4007
rattariwala@aimmedicalimaging.com

Additional identifiers

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

Primary study design

Observational

Study design

Single centre observational longitudinal case control study

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

Questionnaire answers will be tabulated to assess for change

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

V6H 1G9

Sponsor information

Organisation

AIM Medical Imaging (Canada)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

AIM Medical Imaging (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration