Assessment of the alignment of the Atlas and surrounding tissues in chronic whiplash associated disorder.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Observational non invasive

Summary

ID

NL-OMON56685

Source
ToetsingOnline

Brief title
MRAtlas

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

Synonym
neck sprain, Whiplash

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: AMC foundation

Intervention

Keyword: Alignment, Atlas, Position, Whiplash

Outcome measures

Primary outcome

The main primary endpoints are the repeatability of the assessment of the position and alignment of the Atlas (C1) as measured by the angles between the atlas and the surrounding vertebrae in healthy control participants, and the difference in atlas geometry between the two patient groups and the healthy control participants.

Secondary outcome

Secondary endpoints include the assessment of the fat percentage of the suboccipital muscles and the blood flow in the carotid and vertebral arteries, as well as the quantification of differences between the groups. The study's secondary endpoint is established through a neurological examination, physical asymmetry test and questionnaires. Questionnaires are utilized to obtain a quantitative indication of participants' pain experiences, subsequently allowing correlation with the position of the atlas. Additionally, the differences in all these parameters between before and after physiotherapy will be quantified.

Study description

Background summary

Whiplash describes the mechanism of injury consisting of acceleration-deceleration mechanisms of energy transfer to the neck, which can

lead to various bone or soft tissue injuries and associated symptoms. One of the possible causes of these chronic complaints may be that the soft tissue structures are affected. Recent research has shown increased levels of fat infiltration into the muscles and decreases in muscle volume and cross-sectional area (CSA). However, these findings do not fully explain the pain and other complaints. In addition to the soft tissue structures, bony structures, such as the cervical spine, can also be injured by whiplash. However, until now little attention has been paid to the cervical spine, mainly focusing on fractures, but without regard to the position and alignment of the atlas and dens (C1 and C2). The movement of the cervical spine has been studied previously, mainly using CT and MRI. These studies have shown that it would be efficient to study the movement of the cervical spine three-dimensionally. To determine the displacement and movement of the atlas, anatomical points were visually selected to create a local coordinate system. This local coordinate system in combination with automatic segmentation was used to quantify the movements and displacements of the cervical spine. However, the alignment of the Atlas in a neutral position has not yet been investigated. The coordinate system mentioned above may provide insight into the position and alignment of the Atlas.

Study objective

The aim of this study is to assess the position and alignment of the Atlas, as measured by the angles between the atlas and the surrounding vertebrae in healthy participants, patients with tension headache, and patients with chronic whiplash-associated disorder (WAD) (grade 1 or 2), and to correlate outcome measures such as pain intensity, neck restriction, daily activities, overall improvement, and quality of life. Additionally, the effect of physiotherapy on the position and alignment of the Atlas and surrounding tissues will be studied.

Specifically, our objectives are:
i. To investigate the feasibility and repeatability of advanced MRI measurements in 30 healthy control participants aged 18-75.

ii. To evaluate the position and alignment of the Atlas and surrounding tissues using MRI in patients with chronic WAD, comparing them to patients with tension headache and healthy control participants.

iii. To correlate these MRI parameters with neurological examinations, physical asymmetry and questionnaires (patient-reported outcome measures) in patients with WAD and tension headache, aiming to assess sensitivity. Additionally, we will study the effect of physiotherapy on the MR outcome measures and other test outcomes mentioned above.

Study design

2-way prospective observational repeatability study.

Study burden and risks

Participants will be asked to visit the hospital one or two times. During these visits an MRI acquisition is performed in rest. All participants are also asked to complete questionnaires and undergo a neurological examination. There are no medical risks associated with this study. The MRI scan is safe and painless. An MRI scan does not emit ionizing radiation and no drugs will be administered. The scanner does make a lot of noise, so we will give the participants hearing protection to reduce the noise. There is a significant time investment on behalf of the participants, since most of the participants are required to visit the institute on two occasions. Healthy participants visit the institute twice, with the first visit lasting about 3 hours and the second 1.5 hours. For patients undergoing physiotherapeutic treatment, the second visit lasts about 2 hours (because, in addition to the MRI, a number of other tests are repeated). Participants will receive reimbursement for their travel and parking costs. Participants have no direct benefit by participating in this study. A group-related benefit of this observational study is that in the future these MR acquisitions might become a valuable tool in research and management of chronic whiplash associated disorder.
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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Phase 1
Control participants
• Healthy individuals
• Ability to follow test instructions
• Aged between 18 - 75 years

Phase 2
Chronic Whiplash Associated Disorder
• Healthy individuals
• Ability to follow test instructions
• WAD 1 or 2 Diagnosis
• Aged between 18 - 75 years
• Individuals who are planning to start physiotherapy

Tension headache
• Healthy individuals
• Ability to follow test instructions
• Diagnosis Tension headache
• Aged between 18 - 75 years
• Of which 15 are planning to start physiotherapy.

Exclusion criteria

• Inability to provide informed consent
• Have a history of claustrophobia
• Patient/ participant is not eligible to follow instructions
• Contra-indication for MRI (e.g., pacemaker, Claustrophobia; See F1 vragenlijsten screening MRI Amsterdam UMC)
• Being under investigation for non-diagnosed disease at the time of investigation

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2023
Enrollment:	0
Type:	Anticipated

Ethics review

Approved WMO Date:	20-03-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-08-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-10-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL84857.018.23