MaNeS (Maastricht Neck Study): development of chronic disability in neck pain patients after a motor vehicle accident

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Primary objective: - Objective the natural course of active- and passive range of motion and principally the diffenence score between active and passive cervical range of motion after a whiplash trauma.Secundary objectives: - To investigate the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON33117

Source
ToetsingOnline

Brief title
MaNeS

Condition

- Joint disorders

Synonym
acceleration-deceleration trauma of the neck, Whiplash Associated Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: disability, neck, range of motion, whiplash

Outcome measures

Primary outcome

- Active- and passive cervical range of motion measured with the 3Space InsideTrak HP system (Polhemus Navigational Division, Kaiser Aerospace, Vermont, USA).

Secondary outcome

Investigated will be the correlation between active- and passive movement restraints of the neck and the following factors: pain and the related thoughts and feelings, restraints of the neck, state of mind, memory and attention, events of the last year, and complaints as a result of the trauma.

- Pain and the belonging thoughts and feelings, measured by the NRS, TSK and PCS
- Restraints of the neck will be measured by means of NDI
- State of mind will be measured by CES-D, TAS and EPQ
- Memory and attention will be measured by CFQ
- Events of the last year will be measured by the Holmes-Rahe schaal
- Quality of life will be measured by the RAND-36
- Complaints as a result of the trauma will be measured by the PSS-SR

Study description

Background summary

Neck complaints are often caused by motor vehicle accidents and particulary after rear-end collision.
Patients complain about neck pain after a whiplash trauma, which lead to mobility restrictions of the cervical spine.
It is estimated that 20% develops a chronic pain disorder after 1 year, called a chronic whiplash syndrom. The primary objective of the previous study was to objective the active- and passive flexion, backward flexion, and rotation to both sides by a quantitative method. Up till now, there is a lack of prosepctive systematic research of active- and passive cervical movement restrictions in whiplash patients on the long term.

Study objective

Primary objective:
- Objective the natural course of active- and passive range of motion and principally the diffenence score between active and passive cervical range of motion after a whiplash trauma.

Secundary objectives:
- To investigate the predictive value of active-and passive range of motion and chronicity.
- To investigate the correlation between the degree of restriction of the active and passive backward flexion for developing chronicity.
- To investigate the correlation between the possible predictive factors pain, ideas and feeling about pain, memory and attention, events of the last year and complaints after the motor vehicle accident and chronicity.

Study design

This is a prospective cohort study which is a continuation of an earlier cohort study. In this study it was examined which factors predict chronicity of neck complaints after a whiplash trauma. The range of motion is measured at time moment t=0. In this study the measurement procedure will be repeated.

Study burden and risks

The nature of burden and risks consists of:
- telephonic screening: 10 minutes
- measurements of cervical movements: 30 minutes
- fill out questionnaire: 45 minuten

In total, time investment will be 1 hour and 25 minutes. This includes filling out the questionnaire by the patient and the measurements.

There are no risks associated with this measurment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients which underwent a movement measurement of the cervical spine on moment t<=0.

Exclusion criteria

- Fracture or dislocation of the cervical spine in the time between measurement 0 and 2
- Pregnancy
- The patient developt cognitive disabilities which could influence filling out the

quenstionnaire

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2009
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	14-09-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCTnummernognietbekend,welgeregistreerdinclinicaltrials.gov
CCMO	NL28336.068.09