Towards an Objective Approach of traumatic and non-traumatic chronic neck pain

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON36540

Source
ToetsingOnline

Brief title
Rotterdam Neck Study (RNS)

Condition

- Other condition

Synonym
traumatic and non-traumatic chronic neck pain; neck pain

Health condition

stoornissen van het houdings- en bewegingsapparaat

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cognitive impairments, eye movements, neck pain profile, proprioception

Outcome measures

Primary outcome

The primary study parameter is the gain (ratio between eye and stimulus movement) of the cervico-ocular reflex (COR), the vestibulo-ocular reflex (VOR) and the optokinetic reflex (OKR) in three different groups before and after an intervention. In addition, the relation to the age of the patient will be taken into account, because the gain of the COR increases with age.

Secondary outcome

The secondary study parameters are:

1. Active cervical range of motion (CROM device), Joint position error after active rotation of the cervical spine (customized camera setup)

2. Different questionnaires:

• Neck Disability Index (Dutch version) (Vernon and Mior, 1991)

• Short Form Health Survey (SF 36) (dutch) (Ware and Sherbourne, 1992)

• EuroQol-instrument (Dutch Version) (EQ-5D)

• Visual Analogue Scale (VAS)

3. Stroop test, Trail making test (version A and B)

4. Saccadic eye movements

Study description

Background summary

Determination of the severity of complaints of patients with chronic traumatic and non-traumatic neck pain is difficult because of its multifarious nature. Clinical assessment is either based on functional impairments (e.g. diminished range of motion, loss of strength) or on subjective symptoms like pain, fatigue and diminished concentration. Especially subjective symptoms like disturbances in postural stability, eye movement control and diminished concentration are difficult to quantify objectively. However, neurophysiologic developments may provide a method to quantify these *sensorimotor symptoms*. In previous studies it was hypothesized that sensorimotor dysfunction may be caused by altered proprioception in the cervical spine. Although straightforward measurement of proprioception is still not possible, neurophysiologic research revealed that the cervico-ocular reflex (COR) receives sensory input from neck proprioception. Changes in COR are likely to reflect changes in neck proprioception.
Our hypothesis is that reflexive eye movement measurements can assist to make the connection between functional impairments and symptoms for chronic neck pain patients. Recording of eye reflexes might help to objectively assess the severity of complaints of neck pain patients.

Study objective

The main objective is to develop an objective symptom profile of chronic neck pain patients which addresses more facets of the health problem, including sensorimotor dysfunction. The first stage is the establishment of an objective quantification of sensorimotor dysfunction.

Questions:
1. Is there a significant difference between the gain (ratio between eye and stimulus movement) of the cervico-ocular reflex (COR), the vestibulo-ocular reflex (VOR) and the optokineticreflex (OKR) in subjects (aged 18-60) with and without chronic neck pain?
2. Is there a correlation between the synergy of the gain of the eye reflexes (COR, VOR and OKR) and cervical functionality (range of motion and joint reposition error)?
3. What is the relationship between degree of synergy of the gain of the eye reflexes (COR, VOR and OKR) and improved impairments (VAS, SF36, Neck Disability Index, EQ-5D, Trail making test a;b and Stroop test)?
4. Can the degree of synergy of the gain of the eye reflexes (COR, VOR and OKR) be influenced by a therapeutic intervention (multidisciplinary rehabilitation program)?
5. Does a change in the synergy of the gain of the eye reflexes (COR, VOR and

OKR) by a therapeutic intervention influence the improved impairments (VAS, SF36, Neck Disability Index, EQ-5D, Trail making test a&b and Stroop test) with a clinical important change?
6. Is the degree of synergy of the gain of the eye reflexes (COR, VOR and OKR) in subjects with a traumatic neck pain different to the degree of synergy of the gain of subjects with non-traumatic neck pain?

Study design

The objective described above will be investigated in a longitudinal intervention study of 60 patients with neck impairments of traumatic and non-traumatic origin between the age of 18 and 60 years. All patients included will first receive usual care (e.g. physiotherapy) (non-intervention group) and later multidisciplinary therapy (intervention group) .The multidisciplinary therapy will be performed by therapists and psychologists of the Spine & Joint Centre.
All patients are included by a diagnostic screening performed by medical doctors of the Spine & Joint Centre. Our measurements will not interfere with the multidisciplinary therapy, nor influence any other medical care.
All patients will be measured four times:
The non-intervention group will be measured twice with an interval of eight weeks while they are waiting for the start of the therapy.
As baseline measurement of the intervention group the second measurement at the end of the waiting period is used. The second measurement will be after eight weeks of multidisciplinary therapy. The last measurement will be three months after the finishing of the therapy period. At the Spine & Joint Centre, the patients will be asked to fill in questionnaires.

Intervention

In the present therapy protocol of the Spine & Joint Centre, cognitive behavioural principles are applied to stimulate patients to adopt adequate behaviour aimed at physical recovery. The program, which is no isolated study design, but part of regular care, consists of 16 sessions of 3 hours each, over an 8-week period (total of 48 hours). Patients are divided into groups of 6 patients accompanied by three therapists and a psychologist. Each session includes training time (1 hour), a group lesson (1 hour) and individual coaching of the patient (1 hour). The program is based on the most recent state of the art en is partly adopted from *Whiplash, Headache and Neck Pain* (Jull et al., 2007). Beside this treatment no other therapy is given.

Study burden and risks

There are no risks related to this study. There are no related physical of psychological side effects to the measurements.
The burden of participating is just the invested time. The subjects with neck

pain undergo four times measurements which last approximately an hour each. By combining the moment of measuring with other appointments at the Spine & Joint Centre, the extra time of travelling will be minimized.

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

Subjects are included if the they have chronic non-traumatic neck pain or chronic neck pain due to a trauma (e.g. whiplash associated disorders). All of the subjects with neck pain have admission to join the therapy in the Spine & Joint Centre.
Only adults (both males and females) under 60 years of age will be included. Subjects should be physically able to undergo COR, VOR and OKR measurements (sitting in a chair for 30 min; biting on a bite-board; staying comfortabel in a dark room). Vision should be good enough to be able to trace a laser dot on a dark background without glasses. Likewise, they should be

able of understanding and filling in the questionnaire and giving informed consent.
The subjects within the control group should have no complaints of the cervical spine at all.
All subjects, except the ones selected for the traumatic group, should have no history of a car accident.

Exclusion criteria

Subjects should not use medication that influences alertness or balance (e.g. benzodiazepines, barbiturates), they should not suffer from any neurological disorder and have no vestibular problems.
All subjects with a history of a neck trauma unlike due to a car accident are excluded.

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:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2011
Enrollment:	90
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-04-2012
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL34790.078.11