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Neck movement and eye function

Submission date	Recruitment status	[_] Prospectively registered
23/06/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/06/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/11/2017	Signs and Symptoms	

Plain English summary of protocol

Background and study aims
Neck pain is a very common condition, which can be cause great discomfort and restriction of movement. Patients with neck pain often have visual problems however the reason for this is unknown. One possibility is that the amount of neck movement a person undertakes can influence the eye function. Many patients with neck pain may move their necks less to avoid pain, which may be causing the visual problems. The aim of this study is to look at whether a lot of movement or restricted movement of the neck has an effect on eye function in healthy people with no neck pain, to try to find the out if there is link between neck movement and visual problems.

Who can participate?
Adults with no neck pain who are able to move their necks freely and have normal or corrected-to-normal vision

What does the study involve?
Participants are randomly allocated to undertake two tests spaced one week apart in a different order. Before and 20 minutes after each test, participants have their eye function (measuring of the eye stabilization reflexes) measured. One test involves moving the neck around extensively for 20 minutes. The other test involves wearing a stiff neck collar that restricts movement for one hour.
The measurement of eye function will be in a darkened room and lasts around 20 minutes. It involves having to look straight forward while the chair they are sitting on is rotating, while the position of their eyes is measured with an infrared eye tracking device. Two weeks later, 11 participants return to repeat the condition with the neck collar, after wearing it for two hours. The eye function tests are repeated before and 20 minutes after wearing the collar.

What are the possible benefits and risks of participating?
There are no direct benefits for participants taking part in this study.

Where is the study run from?
Erasmus MC (Netherlands)

When is the study starting and how long is it expected to run for?
August 2014 to May 2015

Who is funding the study?
Erasmus MC (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2016_6

Study information

Scientific Title
The influence of cervical movement on eye stabilization reflexes: a randomized cross-over trial

Study objectives
The aim of this study is to investigate the influence of the amount of cervical movement on the cervico-ocular reflex (COR) and vestibulo-ocular reflex (VOR) in healthy individuals.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ethical board of the Erasmus MC, 19/07/2011, ref: MEC-2011-273

Study design
Single-centre randomised cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Neck pain

Interventions
In the main experiment, two types of intervention are applied to all participants in a cross-over design: hypokinesia and hyperkinesia. Directly before and after the intervention, the eye stabilization reflexes and the active range of motion are measured.

In the hypokinesia intervention, the neck is immobilized by using a stiff neck collar (size 4, Laerdal Stifneck® Select™) for one hour.

In the hyperkinesia intervention, active neck movement in all possible directions of movement is evoked by having the participants move their neck excessively in all directions for twenty minutes.

Each participant receives both interventions on two different days separated by 6 or 7 days. The order of the two interventions was pseudo-randomized and balanced across participants.

In the replication experiment, eleven participants wear the neck collar for two hours (prolonged hypokinesia). This experiment takes place two weeks after the end of the main experiment.

Intervention Type
Behavioural

Primary outcome measure
Amplitude of the cervico- ocular reflex (COR) and vestibulo-ocular reflex (VOR) is measured with a rotational chair with infrared eye tracking device pre and post each intervention.

Secondary outcome measures
The amount of the active cervical range of motion (CROM) in both the horizontal and vertical plane was also measured device (Performance Attainments Associates, USA) pre and post each intervention.

Overall study start date
01/08/2014

Completion date
01/05/2015

Eligibility

Key inclusion criteria
1. 18 years or older
2. No neck pain
3. Able to move their neck
4. Able to sit on a chair for 20 minutes
5. Normal or corrected-to-normal visual acuity

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Neck pain
2. History of neck trauma
3. Use of tranquilizing medication

Date of first enrolment
01/12/2014

Date of final enrolment
01/05/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus MC
Department of Neuroscience
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Sponsor information

Organisation
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Sponsor type
University/education

Website
www.erasmusmc.nl

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medisch Centrum

Alternative Name(s)

Erasmus Medical Center, Erasmus MC, Erasmus Universitair Medisch Centrum, Erasmus University Medical Center, Universitair Medisch Centrum Rotterdam, Erasmus Universitair Medisch Centrum Rotterdam, EMC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Publication and dissemination plan
The authors intend to publish the results of the study in the autumn of 2016 in the journal 'Archives of Physical Medicine and Rehabilitation'

Intention to publish date
01/08/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2018		Yes	No