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Balance and neck sensitivity in patients with uncomplicated neck pain

Submission date	Recruitment status	[ ] Prospectively registered
08/10/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/11/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/12/2020	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Cervicocephalic kinesthetic sensibility and postural balance in patients with non-traumatic chronic neck pain

Study objectives
The aim of the study is to investigate the head repositioning accuracy (HRA) and standing balance among patients with non-traumatic chronic neck pain. A working hypothesis formed the basis for the study: disturbed HRA and altered postural control will be present among patients with non-traumatic chronic neck pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethical Board of the Chiropractic Association of Sweden and Institutional Review Board of the Scandinavian College of Chiropractic in accordance with the Declaration of Helsinki gave approval on the 12th September 2007 (ref: HRA/CSP2).

Study design
Prospective pilot observational diagnostic accuracy study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Mechanical non-traumatic chronic neck pain

Interventions
A convenience sample of 30 participants will be invited to participate in the study. The participants will take part in ONE observation consisting of two tests: HRA and CSP. During the HRA test the participant will execute 60 movements and it is estimated to take 20 minutes. During the CSP test the participant will execute four different test series and it is estimated to take 10 minutes. There will be no follow-up observations.

Head Repositioning Accuracy (HRA):
Briefly, an ice hockey helmet with a connected laser pointer will be positioned on the head of each subject and adjusted for individual fit. A laser pointer is located at a 90° angle toward a mobile coordinate system. The position of the laser pointer is calibrated by the investigators so that the path of the laser pointer is at a right angle to the frontal plane, and at a distance of 100

cm to the approximate axis of motion from the co-ordinate system. The eyes will be occluded with a sleeping mask during the procedure. The participant will be asked to memorise the neutral position in order to duplicate it after an active, sub-maximal movement of the head. The mobile target will be calibrated after each repositioning movement so that the laser pointer is projected at the centre of the target. Following pre-recorded instructions, the subject will be instructed to move the head in a specific direction and then reposition the head to the neutral position. The investigators will register the location of the pointer when the position is stabilised (time standardised by pre-recorded instructions). The distance from the original position to the position at repositioning is measured. Each directional movement is repeated consecutively ten times and the average of the assessments is used as result in that direction. Head movements are done in right and left rotation, and extension and flexion. Four head movements are used. 10 movement-repositionings in right rotation, then 10 in left rotation, 10 in flexion then 10 in extension, for a total of 40 movement-repositioning tasks. The HRA procedure is performed on all participants by the same investigator.

Computerised Static Posturography (CSP):
This is used to assess balance in this study. A computerised, stable force platform (model FP4), developed for jump and balance testing, measured postural sway and changes in standing balance under altered visual conditions. The assessment of postural performance is performed in a calm, undisturbed room. The subjects will be standing barefooted on the force platform with the feet parallel to the y-axis of the platform and with the arms along their sides. The subjects feet are repositioned on the force platform for every test using a paper traced foot position based on the "comfortable position". Each subject is tested for static balance using a standing Rombergs test first for 60 seconds with eyes open and then immediately followed by 60 seconds with occluded eyes. In the tests with eyes open, the subject focuses on a black dot, with the diameter of 5 centimetres, which is located on the wall approximately 3 metres away and adjusted to match the height of the subjects eyes. The participants are instructed to keep their arms along the body and keep as still as possible during the measurement. The total distance covered by the projection of the centre of the gravity during the each registration period is measured and reported. The force platform was calibrated according to manufacturers recommendations prior to each trial and performed on all participants by the same investigator. The calibration of the platform will be performed according to The Committee for Standardisation of Stabilometric Methods and Presentations.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Participants with mechanical non-traumatic chronic neck pain will display disturbed cervicocephalic kinesthetic sensibility as measured with HRA and postural balance as measured with CSP, measured at one occasion in the beginning of November.

Secondary outcome measures
Psychometric Visual Analogue Scale (VAS) to verify if there is correlation between the pain level and the functional impairment, measured at one occasion in the beginning of November.

Overall study start date
22/10/2008

Completion date
05/11/2008

Eligibility

Key inclusion criteria
1. Aged 30 - 55 years
2. Male or female
3. Neck pain prolonged more than 12 weeks (not valid for participants in the control group who will be healthy individuals)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30 subjects

Total final enrolment
29

Key exclusion criteria
1. Neck trauma
2. Chronic low back pain (greater than 3 months)
3. Arthrodesis in foot or ankle
4. Evident impaired function/pain in foot or ankle
5. Evident impaired function/pain in knee
6. Evident impaired function/pain in hip
7. Diastolic blood pressure greater than 110 mmHg
8. Pregnancy
9. Drug abuse
10. Aid for walking or standing
11. Known disease that affects nervous system (e.g. multiple sclerosis [MS], stroke, Parkinson's disease)
12. Known disease that affects vestibular apparatus (e.g. Meniere's disease, benign paroxysmal position vertigo [BPPV])

Date of first enrolment
22/10/2008

Date of final enrolment
05/11/2008

Locations

Countries of recruitment
Sweden

Study participating centre
Rasundavagen 101
Solna, Stockholm
Sweden
16957

Sponsor information

Organisation
Scandinavian College of Chiropractic (Sweden)

Sponsor details
Rasundavagen 101
Solna, Stockholm
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Sponsor type
University/education

Website
http://www.kiropraktik.edu/

ROR
https://ror.org/023j1w312

Funder(s)

Funder type
University/education

Funder Name
Scandinavian College of Chiropractic (Sweden)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/06/2009	30/12/2020	Yes	No