ISRCTN88585962 https://doi.org/10.1186/ISRCTN88585962

Effect of manual versus mechanically assisted manipulations of the thoracic spine in neck pain patients

Submission date
27/11/2012

Recruitment status
Stopped

Registration date
10/01/2013

Overall study status
Stopped

Last Edited
11/08/2015

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Previous studies have shown that manipulations of the neck (cervical spine) in combination with exercises have the best outcome in patients with neck pain. However, there are some small risks associated with cervical spine manipulations. Consequently an alternative treatment method has been developed. Studies have shown a positive outcome of upper back (thoracic spine) manipulations for neck pain. These manipulations can be delivered manually or carried out by using a mechanical medical device. Within this study a mechanical medical device called the iQ Impulse will be used to administer the manipulations. This device was tested, certified and registered at the British Standards Institution (CE 55616) and is safe for treatment use. The aim of this study is to compare the effect of manually versus mechanically delivered manipulations.

Who can participate?
Age >18 years old, male and female with neck pain (acute or chronic) Grade I or II and able to speak and read German or English

What does the study involve?
The participants will be randomly divided into two groups:
Group A: 40 patients will receive manual manipulations and exercises
Group B: 40 patients will receive mechanical manipulations and exercises
To participate in this study you should attend four appointments. During the first session you will be given a standardized physical examination, be asked to fill out questionnaires, receive the first manipulation and given a home exercise program. The type of manipulation (mechanical versus manual) to be given to your thoracic spine will be made beforehand. This distribution is made using a computer program. Neither the study administration nor the participant may influence the allocation to the treatment group. The next two appointments will each be scheduled from two to four days apart and you will be asked to fill out the questionnaires again and you will receive more manipulations. One year after the first treatment you will be asked to attend an appointment to fill out the questionnaires for the last time. Within the first appointment you will also receive a home-program, this will be explained to you in detail by a member of the research team. The program consists of seven exercises, which you should

execute frequently at home. To keep track of the exercise program, you are asked to mark the days you carried out the exercises on a training schedule.

What are the possible benefits and risks of participating?
Due to the manipulation in combination with the home exercise program your neck pain problems may decrease. Because of your participation future neck pain patients may benefit from this outcome as well from the new information we learn from doing this research. This research may provide new knowledge for a more effective treatment for neck pain patients. The risks associated with this study are small and particular care has been taken to minimize all possible risks by performing a thorough physical examination at the beginning of this study. However it is possible that you may experience some minor muscle pain or soreness from the manipulation and/or with the exercise program but this should be temporary and carries no harm. In the very unlikely event that you experience something more serious or longer lasting, or if you have any questions about this study, a medical specialist can be contacted. Your participation in this study is optional. If you decide not to take part, there will be no disadvantages to you for your current or future medical care. As well, you are free to withdraw from the study at any time without any disadvantage to your medical care. You will not be asked to justify your reason(s) for withdrawing. If you should withdraw, only the data collected up to that time will be included in the study. The participants will not receive any compensation for participation. In the unlikely event that you experience any injury or damages related to your participation in this study the Balgrist University Hospital will cover the appropriate costs through its insurer.

Where is the study run from?
The study is conducted at the Division of Chiropractic Medicine at the Balgrist University Hospital

When is the study starting and how long is it expected to run for?
The study will begin in February 2013 and continue until 2016. The participants will be recruited over a period of 2 years.

Who is funding the study?
Balgrist University Hospital (Switzerland).

Who is the main contact?
Anke Langefeld
ankelangenfeld@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Kim Humphreys

Contact details
Balgrist University Hospital
Forschstrasse 340
Zurich
Switzerland
8008

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of manual versus mechanically assisted manipulations of the thoracic spine in neck pain patients: a randomized controlled trial

Study objectives
1. Neck pain patients benefit from thoracic spine instrument assisted mechanical manipulations performed by the Impulse iQ®.
2. There is no a difference in pain, disability and self-reported improvement between the treatment groups treated with the Impulse iQ® or manual manipulations.

On 22/01/2013 the overall trial start date was changed from 12/11/2012 to 01/02/2013.

On 18/07/2014 the following changes were made to the trial record:
1. The public title was changed from 'Manual vs mechanically performed manipulations of the thoracic spine in neck pain patients' to 'Effect of manual versus mechanically assisted manipulations of the thoracic spine in neck pain patients'
2. The scientific title was changed from 'Manual vs mechanically performed manipulations of the thoracic spine in neck pain patients: a randomized comparative effectiveness trial' to 'Effect of manual versus mechanically assisted manipulations of the thoracic spine in neck pain patients: a randomized controlled trial'

Updated 11/08/2015: the trial was stopped due to a participant recruitment issue.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Canton of Zurich Ethics Committee, 14/09/2012, Ref. Nr. KEK-ZH-Nr. 2012-0248

Study design
Randomized comparative effectiveness trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Neck pain

Interventions
Trial comparing the treatment outcomes of manual and instrument assisted mechanical manipulations of the thoracic spine for neck pain patients.

A: Manual manipulations of the thoracic spine

B: Mechanically applied manipulations of the thoracic spine

Both groups will receive a total of three manipulations. Within the first treatment session they will also receive a standardized home programme.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 22/01/2013:
Visual Analogue Scale (VAS)

Previous primary outcome measures until 22/01/2013:
1. Neck Disability Index (NDI)
2. European Quality of Life 5 Dimensions 5 Levels (EQ-5D-5L)
3. Patients Global Impression of Change Scale (PGIC)
At all four appointments, before the treatment.

Secondary outcome measures
Current secondary outcome measures as of 22/01/2013:
1. Neck Disability Index (NDI)
2. European Quality of Life 5 Dimensions 5 Levels (EQ-5D-5L)
3. Patient's Global Impression of Change Scale (PGIC)
At all four appointments, before the treatment.

Previous secondary outcome measures until 22/01/2013:
1. Impulse iQ® Adjusting Instrument variables
1.1. Time

1.2. Frequency
1.3. Force

Overall study start date
01/02/2013

Completion date
11/11/2016

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Age >18 years old, either sex
2. Neck pain (acute or chronic) Grade I or II
3. Able to speak and read German or English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80 - added 25/11/2013: we will accept participants from physical therapists as well as chiropractors

Key exclusion criteria
1. Severe disorders of the cervical spine such as disc prolapse
2. Spinal stenosis
3. Postoperative conditions in neck and shoulder areas
4. History of severe trauma
5. Spasmoidic torticollis
6. Frequent migraine
7. Peripheral nerve entrapment
8. Fibromyalgia, shoulder diseases, inflammatory rheumatic diseases, osteoporosis and cancer

Date of first enrolment
01/02/2013

Date of final enrolment
11/11/2016

Locations

Countries of recruitment
Switzerland

Study participating centre
Balgrist University Hospital
Zurich
Switzerland
8008

Sponsor information

Organisation
Balgrist University Hospital (Uniklinik Balgrist) (Switzerland)

Sponsor details
c/o Swanenburg
Forschstrasse 340
Zurich
Switzerland
8008
-
jaap.swanenburg@balgrist.ch

Sponsor type
Hospital/treatment centre

Website
http://www.balgrist.ch/en/

ROR
https://ror.org/02yzaka98

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Balgrist University Hospital (Switzerland)

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?
Protocol article	protocol	27/05/2015		Yes	No