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Effectiveness of cervical osteopathic manipulation techniques of high velocity and low amplitude in patients with whiplash-associated disorders

Submission date
14/05/2014

Recruitment status
No longer recruiting

Registration date
21/07/2014

Overall study status
Completed

Last Edited
18/12/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Whiplash is a neck injury caused by a sudden movement forward, backward or sideways movement of the head. It often happens after a sudden impact from, for example, a road traffic accident and results in damage to the ligaments and tendons in the neck. Road traffic accidents and their effects on social-health costs are an important problem for society. Whiplash and whiplash associated disorders (WAD for example pain, reduced range of neck movement, neurological damage and even fracture) are the number one reason for people visiting the emergency room after being involved in a road traffic accident. Osteopathic high velocity, low amplitude (HVLA) techniques, and mobilization techniques of the cervical spine, either alone or combined with other treatments, are methods used to treat neck problems. Both treatments result in similar short term changes, but there is not enough data to assess their long-term effects, making it difficult to develop the best technique and when and how long the treatments should be applied. The aim of this study is to precisely and objectively contribute to the knowledge available on how good HVLA techniques are at treating whiplash and WAD. HVLA techniques are compared with other physiotherapy techniques, looking at how long the treatments are needed, the degree of pain relief they offer, how much they improve the function and mobility of the spine and analysing radiological changes in cervical curvature.

Who can participate?
Patients aged 18 to 65 with WAD admitted to the Osteopathic Centre in Terrassa.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in the study group receive HVLA treatment and the control group receive conventional manual osteopathic therapy and therapeutic exercises. The results from the two groups are then compared to assess how well they treat whiplash and WAD.

What are the possible benefits and risks of participating?
Participants are unlikely to directly benefit from the study, but the results could help future sufferers of whiplash, resulting in better management of their symptoms and avoiding excessive procedures. The risks associated with this study are rare and generally mild, but include some neurodegenerative reactions (sweating, low blood pressure, feeling sick and/or rapid heart rate) during, or immediately after, the therapy.

Where is the study run from?
Health Consortium of Terrassa (Spain)

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

Who is funding the study?
The Osteopathic Centre, Terrassa and the Health Consortium of Terrassa (Consorci Sanitari de Terrassa) (Spain)

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
N/A

Study information

Scientific Title
Research project on the effectiveness of cervical OSTEOpathic manipulation techniques of high velocity and low amplitude in patients with whiplash-associated disorders: a Randomized Controlled single-blind Trial

Acronym
OSTEO-RCT

Study objectives
Patients who have suffered cervical whiplash, specific osteopathic techniques to adjust the treatment, of high velocity and low amplitude (SAT-HVLA) of the cervical spine, obtain better results than those treated with combined treatments found in cervical therapeutic exercise manuals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee at the Health Consortium of Terrassa - Terrassa Hospital (Consorci Sanitari de Terrassa Hospital de Terrassa), 20/12/2013

Study design
Randomized controlled single-blind 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Whiplash associated disorders (WAD)

Interventions
The participants are randomised to two groups:
1. Treatment: The technique of choice, will be the Specific Adjusting Technique (SAT). This is a High Velocity Low Amplitude Technique, whose objective is to reverse the injury caused by the trauma.

Throughout the trial we will make three interventions with SAT (one every two weeks)
In the first intervention, we will manipulate the upper cervical segment (C2/C3)
In the second intervention, we will manipulate the low cervical segment (C5/C6)
In the third intervention, we will manipulate the upper thoracic segment (T1/T2)
2. Control: The participants will receive conventional treatment, consisting in manual therapy techniques and therapeutic exercises, over four weeks.

Participants are followed up at 11 days, 30 days, and 110 days after treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 01/02/2017:
1. Functionality (disability), measured using the Northwick Park Neck Pain Questionnaire (NPQ) at baseline, 11 days, 30 days, and 110 days after treatment
2. Cervical mobility, measured using the Cervical Range Of Motion Instrument (CROM) at baseline, 11 days, 30 days, and 110 days after treatment
3. Radiological changes in the cervical curvature, measured using the Cobb method (COOB) at baseline and 30 days after treatment

Previous primary outcome measures:
1. Functionality, measured using the Northwick Park Neck Pain Questionnaire (NPQ)
2. Cervical mobility, measured using the Cervical Range Of Motion Instrument (CROM)
3. Radiological changes in the cervical curvature (CA)

Secondary outcome measures
Current secondary outcome measures as of 01/02/2017:
1. Pain, measured using the Visual Analogue Scale (VAS) at baseline, 11 days, 30 days, and 110 days after treatment
2. Anxiety, measured using the Hospital Anxiety and Depression Scale (HAD) at baseline, 30 days, and 110 days after treatment
3. Depression, measured using the Hospital Anxiety and Depression Scale (HAD) at baseline, 30 days, and 110 days after treatment

Previous secondary outcome measures:
1. Quality of life
2. Mobility of the cervical spine
3. Lordosis of the cervical spine

Overall study start date
22/05/2014

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Patients ages 18 to 65 years presenting whiplash syndrome (WAD)
2. They must have radiological studies (A-P and lateral projections) with previous signed informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
148

Key exclusion criteria
1. Chronic cervical pain
2. Bone pathology
3. Systemic pathologies (acute infections, cancerous or inflammatory processes)

Date of first enrolment
22/05/2014

Date of final enrolment
01/07/2015

Locations

Countries of recruitment
Spain

Study participating centre
The Osteopathic Centre, Terrassa (Centre d'osteopatia Terrassa)
Spain
08224

Sponsor information

Organisation
The Osteopathic Centre, Terrassa (Centre d'osteopatia Terrassa) (Spain)

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Sponsor type
Hospital/treatment centre

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Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Osteopathic Centre, Terrassa (Centre d'osteopatia Terrassa) (Spain)

Funder Name
Health Consortium of Terrassa (Consorci Sanitari de Terrassa) (Spain)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal in 2017.

Intention to publish date
01/06/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		31/01/2017	15/02/2017	No	No