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Comparing different diagnostic tests to determine what back problem patients may have: A study protocol

Submission date
24/05/2017

Recruitment status
No longer recruiting

Registration date
24/05/2017

Overall study status
Completed

Last Edited
24/05/2017

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Musculoskeletal disorders (MSD) include different disorders such as osteoarthritis, rheumatoid arthritis, low back pain, neck pain and many more. They account for a large part of global disability and are predicted to increase over the next few years. Recent studies have stated that it is urgent to prevent and control the growth of musculoskeletal disorders by experts in this field; therefore there is a need for changes in the health system and research to understand the management and prevention of such MSD. There is a need to know whether people suffer from a certain “musculo-skeletal” health problem and what tests can be performed by clinicians to detect it in order to direct more research. The aim of this study is to evaluate the accurateness of using a mechanical chiropractic device using different diagnostic tests.

Who can participate?
Adults aged 18 to 70 years old who have a history of back pain.

What does the study involve?
Participants who attend the clinic for back pain undergo two different tests. They first undergo an assessment of their muscles using the modified ankle rigidity test and a leg length inequality test using a motion capture device. They then undergo a chiropractic procedure using a mechanical device that is applied to their neck area. They then repeat the measurements. After this, they undergo an x-ray. The results from the tests are compared to the results from the x-ray to see if the are any differences.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating in this study.

Where is the study run from?
1. Centre Quiropràctica Girona (Spain)
2. Gabinet Mèdic de Diagnosi i Tractament: GD mèdic Girona (Spain)

When is the study starting and how long is it expected to run for?
March 2017 to December 2018

Who is funding the study?
Investigator initiated and funded (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
study protocol

Study information

Scientific Title
Prediction of the axial rotation of the atlantooccipital joint by means of the modified manual ankle rigidity test and radiography: Study protocol of a randomized double-blind controlled trial

Study objectives
The aim of this study is to evaluate the accurateness of the predicted rotational degree set on a mechanical chiropractic device by the main assessor in 50 subjects through the elicited immediate neurophysiological response as measured by one diagnostic test (modified ankle rigidity test) as compared to the radiographic measurement of the atlantooccipital joint.

Another diagnostic test (leg length inequality test) is used to assess possible changes in (functional leg discrepancy).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Randomized prospective double-blind trial of one diagnostic test as primary outcome compared to radiographic measurement outcomes

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Musculo-skeletal

Interventions
Participants consent to participate in the study and have their medical history and physical examination in order to confirm eligibility.

Participants undergo the treatment session. This starts with an assessment of muscle dysfunction using the modified ankle rigidity test, followed by the leg length inequality test with the motion capture device. Next, treatment is applied with the mechanical chiropractic device applied in their neck area according to some specifications and to the criteria of the main assessor. After each application or attempt, the assessor uses the modified ankle rigidity test to evaluate changes. If no changes are observed, a second attempt is carried out and so on. If changes are observed, the assessor stops treatment and performs the leg length inequality test.

After data is recorded, the assessor and the subject go to the X-ray clinic (Gabinet Mèdic de Diagnosi i Tractament)) to take the radiographic view. The assessor is blinded to the results by not seeing the X-ray at any time. They only position the patient, following similar instructions as described for this purpose and the clinic X-ray technician takes the radiograph. The radiographic equipment is regularly aligned by the clinic owners. The results are kept in the X-ray clinic and at the end of the study they are sent to the independent assessor for evaluation. Then, all the results will be sent to the statistician for compilation.

At this point, there is no follow up for participants except for continuing care under main assessor's private clinic if they decide to.

Intervention Type
Device

Primary outcome measure
Muscle rigidity is measured using the modified ankle rigidity test and Ashworth scale at baseline and after the treatment.

Secondary outcome measures
1. Leg length discrepancy is measured in sub-millimeters using the leg length inequality test at baseline and after the treatment
2. Degrees of rotation of the atlanto-occipital joint are measured using radiographic views at baseline and after treatment

Overall study start date
03/03/2017

Completion date
03/12/2018

Eligibility

Key inclusion criteria
1. Present or past history of back pain
2. Any gender aged from 18 to 70 years old
3. Consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Tumour
2. Spinal fracture
3. Back pain associated with externalized cervical disc herniation
4. Previous back surgery
5. Dizziness and vertigo

6. Spasmodic torticollis
7. Can't sit for more than 30 minutes
8. Received other manual therapies in the previous ten days of the study
9. Under similar care other than the one used in this study in the past.
10. Pregnancy

Date of first enrolment
04/01/2018

Date of final enrolment
03/10/2018

Locations

Countries of recruitment
Spain

Study participating centre
Centre Quiropràctica Girona
Gran Via Jaume I
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Study participating centre
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Sponsor information

Organisation
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Sponsor type
Other

Funder(s)

Funder type
Other

Funder Name
Investigator initated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a BioMed Central journal

Intention to publish date
30/06/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository and will be made available from the main assessor, the independent assessor and the statistician.

IPD sharing plan summary
Stored in repository