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The effect of the spinal mobilization in subjects with acute low back pain

Submission date	Recruitment status	[ ] Prospectively registered
11/03/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/03/2015	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/10/2020	Musculoskeletal Diseases	

Plain English summary of protocol
Plain English summary under review

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
Diffusion of water within lumbar intervertebral discs after a single session of postero-anterior spinal mobilization in subjects with acute low back pain

Study objectives
The objective of our research project is to study the effectiveness of a single session of postero-anterior (PA) spinal mobilization of lumbar vertebrae in patients suffering from acute low back pain. The evaluation of the effectiveness of the PA will be mainly based on the analysis of MRI diffusion-weighted images and the computation of the apparent diffusion coefficient (ADC). Our main hypothesis is that in vivo diffusion of water within lumbar intervertebral discs will be increased at least at the level of the PA pressure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Saint-Luc Hospital and Departmental Ethics Committee (2014/07AOU/419), 06/10/2014, ref: B403201421675.

Study design
Non randomized single-center trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Low back pain (LBP). By definition, LBP is a lumbar pain localization, between the twelfth thoracic vertebra (Th12) and lumbosacral junction, with radiating pain in the gluteal area or towards the knee.

Interventions
During data collection, each subject was assessed by two therapists. The first therapist filled in the Visual Analogue Scale for pain and 2 questionnaires with the subject (Saint-Antoine and DN4). The second therapist, carried out various musculoskeletal clinical tests (flexion, extension and lateral flexion of the trunk in standing) and a neuro-dynamic test (SLUMP test). Then, a first MRI scan of the lumbar region of the subject was carried out. After this first MRI, a spinal mobilization type PA (Maitland) was carried by the second therapist. To complete the data collection, a second MRI scanner, identical to the first, was carried out on the subject within an hour after the spinal manipulation. During this time, all questionnaires (except DN4) and clinical tests are again carried out by the two therapists.

Intervention Type
Procedure/Surgery

Primary outcome measure
We used the diffusion-weighted sequences to quantify the “micro” movements of water molecules within the intervertebral discs (IVDs) of the lumbar spine. The apparent diffusion coefficient (ADC) provides the image of the mobility of water molecules.

Secondary outcome measures
1. VAS: The visual analogue scale is a slider that allows the subject to self-evaluate the pain using a cursor. The patient moves the cursor to the end of "no pain" to the end "worst pain imaginable ". On the back of the slider, the therapist can evaluate the pain felt by the subject, using a scale in millimeters.
2. Trunk flexion before onset of pain: Positioning the patient standing with knees extended. Asked to flex the trunk while specifying it to properly wrap one by one the vertebrae trying to go touch her toes until the onset of pain. Finally, the therapist noted measuring the distance between the fingertips and the ground.
3. Trunk extension before onset of pain: Positioning the patient standing knees, in strict extension. It then requests extension of the column leaving the arms hang vertically. The therapist must be careful to secure the patient's pelvis to look only at the extension of the column. Finally, the therapist noted measuring the distance between the fingertips and the ground.
4. Lateral flexion of the trunk before onset of pain: Measuring the distance over which the hand moves along the lower member in a lateral flexion of the trunk

Overall study start date
06/10/2014

Completion date
30/08/2015

Eligibility

Key inclusion criteria
1. Acute low back pain
2. A period of less than 6 consecutive weeks of pain
3. More than 1 month without pain between the current and previous episodes of low back pain
4. The patient must have had more days without pain than days with pain in the past year

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
n=20

Total final enrolment
16

Key exclusion criteria
1. Aversion to spinal manipulation
2. Patients with chronic low back pain (pain for more than 3 months)
3. Radiating pain below the knees
4. Spine fracture
5. Spine Surgery
6. Osteoporosis
7. Pregnancy
8. Implanted devices that could interact with the magnetic field of the MRI
9. Intolerance using MRI (claustrophobia)
10. Safety issue related to the equipment's weight capacity (obesity)
11. Alcohol or drug abuse, mental illness or lack of cognitive ability

Date of first enrolment
07/10/2014

Date of final enrolment
30/08/2015

Locations

Countries of recruitment
Belgium

Study participating centre
HELHa (Haute Ecole Louvain en Hainaut)
134, rue Trieu Kaisin
Montignies -sur-Sambre
Belgium
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Sponsor information

Organisation
Haute École Louvain en Hainaut

Sponsor details
134, rue Trieu Kaisin
Montignies-sur-Sambre
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Sponsor type
University/education

Website
http://www.helha.be/#1

ROR
https://ror.org/03sfp2d76

Organisation
GEPTO A.S.B.L

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51, Avenue Gambetta
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7100

Sponsor type
Other

Organisation
Siemens s.a. - Healthcare

Sponsor details
123, Guido Gezellestraat
Huizingen
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1654

Sponsor type
Industry

Organisation
GHdC a.s.b.l.

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Intention to publish date

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	29/05/2018	15/10/2020	Yes	No