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

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
11/03/2015		☐ Protocol		
Registration date 23/03/2015	Overall study status Completed	Statistical analysis plan		
		[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

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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 posteroanterior (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 6061

# Sponsor information

#### Organisation

Haute École Louvain en Hainaut

#### Sponsor details

134, rue Trieu Kaisin Montignies-sur-Sambre Belgium 6061

#### Sponsor type

University/education

#### Website

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

#### **ROR**

https://ror.org/03sfp2d76

#### Organisation

**GEPTO A.S.B.L** 

## Sponsor details

51, Avenue Gambetta La Louvière Belgium 7100

## Sponsor type

Other

## Organisation

Siemens s.a. - Healthcare

## Sponsor details

123, Guido Gezellestraat Huizingen Belgium 1654

## Sponsor type

Industry

## Organisation

GHdC a.s.b.l.

#### Sponsor details

3, Grand'Rue Charleroi Belgium 6000

#### 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