ISRCTN13785224 https://doi.org/10.1186/ISRCTN13785224

Shock wave therapy for chronic low back pain

Submission date
20/11/2019

Recruitment status
No longer recruiting

Registration date
04/12/2019

Overall study status
Completed

Last Edited
13/06/2022

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Chronic back pain is defined as pain that persists for 12 weeks or longer, even after an initial injury or underlying cause of acute low back pain has been treated. About 20 per cent of people affected by acute low back pain develop chronic low back pain with persistent symptoms at one year. In some cases, treatment successfully relieves chronic low back pain, but in other cases pain persists despite medical and surgical treatment. Shock wave therapy is a procedure where shock waves are passed through the skin to the affected area using a special device, and ultrasound guidance may be used.
The aim of this study is to assess the effectiveness of Radial Shock Wave Therapy (RSWT) and Focused Shock Wave Therapy (FSWT) and to compare real procedures to sham procedures in the treatment of low back pain. These two types of Extracorporeal Shock Wave Therapy were chosen because of the differences in tissues penetration. Both are increasingly used to treat patients with low back pain, but there was no reliable research that assessed which one is more effective.

Who can participate?
Patients aged 18 and over, both males and females, with chronic low back pain.

What does the study involve?
Participants are randomly allocated to receive RSWT, FSWT, sham RSWT or sham FSWT, 10 times in total. Pain relief and functional improvement are measured before and after treatment and during follow-up visits 1 and 3 months after the end of the study.

What are the possible benefits and risks of participating?
Participants will receive a complete treatment program, which may lead to reduced pain and functional improvement. Risks include temporary pain up to 24 hours after the shock wave procedure.

Where is the study run from?
Opole Medical School (Poland)

When is the study starting and how long is it expected to run for?
June 2018 to August 2020

Who is the main contact?
1. Dr Katarzyna Rajfur
k.rajfur@gmail.com
2. Prof. Jakub Taradaj
j.taradaj@awf.katowice.pl

Study website
http://wsm.opole.pl/3210/5723/projekty-badawcze.html

Contact information

Type(s)
Public

Contact name
Dr Katarzyna Rajfur

ORCID ID
https://orcid.org/0000-0002-0310-6869

Contact details
68 Katowicka Street
Opole
Poland
45-065
+48 (0)506202372
k.rajfur@gmail.com

Type(s)
Scientific

Contact name
Prof Jakub Taradaj

ORCID ID
http://orcid.org/0000-0002-1796-5832

Contact details
Mikołowska 72B Street
Katowice
Poland
40-065
+48 (0)668613945
j.taradaj@awf.katowice.pl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
WPBWF1/18

Study information

Scientific Title
Long and short term clinical, functional and postural outcomes of radial vs. focused extracorporeal shock wave therapy in patients with chronic low back pain

Study objectives
1. Both Radial Shock Wave Therapy (RSWT) and Focused Shock Wave Therapy (FSWT) are effective in pain relief in patients with chronic low back pain
2. The RSWT and FSWT are effective in functional improvement in individuals with chronic low back pain
3. Both RSWT and FSWT improve postural control in subjects with chronic low back pain
4. The RSWT and FSWT improve gait parameters in participants with chronic low back pain
5. According to biological and physical mechanisms, it seams the FSWT promote more effective clinical, functional and postural outcomes compared to the RSWT

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/08/2018, Research Ethics Committee from Opole Medical School (68 Katowicka Street; 45-065; Poland; +48 774410882; biurorektora@wsm.opole.pl), ref: KB/90/FI/2018

Study design
Prospective randomized single-blinded study with follow-up analysis

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
http://wsm.opole.pl/3210/5723/projekty-badawcze.html

Health condition(s) or problem(s) studied

Chronic low back pain

Interventions
After baseline assessments, the participants will be randomly assigned to:
1. FESWT and core stability exercises, or
2. RESWT and core stability exercises, or
3. Sham FESWT and core stability exercises, or
4. Sham RESWT and core stability exercises

The individuals receiving the treatment will be blinded. A computer-generated list of random numbers will be used and concealed from the researchers enrolling and assessing the participants. The outcome assessors and data analysts will be kept blinded to the allocation

The treatment protocol will include core stability training (45 minutes, once a day, five days a week from Monday to Friday) with myofascial relaxation of the erector spinae, activation of the lumbo-pelvic-hip complex and deep muscles, stimulation of proper breathing, dynamic postural exercises, and treatment with RESWT (2 000 shots each session; energy flux density of 0.1 mJ /mm2; frequency of 5 Hz) using a pneumatic device in group A, or treatment with FESWT (1 000 shots each session; energy flux density of 0.15 mJ/mm2; frequency of 4 H) using an ultrasound device in group B. The procedures were performed twice a week (Monday and Thursday) for a period of five weeks (10 procedures in total).

Participants in group C and D were treated with the same core stability training compared to previous groups and additionally with the sham physical procedures. The shock wave therapy was identical to that of group A and B (the sham stimulation was voided of biologically active components by applying a special polyethylene applicator cap, which absorbed energy and limited its propagation to the human tissues) with the same sound signals during the procedure of the pneumatic/ultrasound head and the same technical parameters as in the real procedures.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Pain assessed with the Visual-Analogue Scale and the Laitinen Pain Indicator Questionnaire at baseline, after treatment, and during follow-up visits at one and three months

Secondary outcome measures
Measured at baseline, after treatment, and during follow-up visits at one and three months:
1. Quality of life assessed with the Oswestry and Roland–Morris Disability Questionnaire
2. Posture stability with open and closed eyes measured using posturography
3. Gait analysed using medical treadmill
4. Mobility range in the hip joint on the side of the herniated disc in the course of spinal discopathy measured using the Lasèque test. The starting position is lying down on the back with both legs straight. The examiner then slowly lifts one of the patient’s legs while the knee is straight at the joint until pain occurs. The mobility range is measured in angle degrees using a goniometer
5. Mobility of the lumbosacral spine evaluated using the Schober test. While the patient is in a standing position, the examiner marks 2 points on the patient’s skin: at 10 cm above the line

connecting the posterior superior iliac spines, and then at 5 cm below that line. The patient then slowly bends down as far as possible, while keeping the knees straight. The measurement is made using a tape measure. The obtained result is recorded with an accuracy of up to 0.5 cm

Overall study start date
12/06/2018

Completion date
31/08/2020

Eligibility

Key inclusion criteria
1. Patients with discopathy of the L5-S1 spine segment with chronic pain lasting more than three months (diagnosis based on magnetic resonance imaging examination to determine the advancement of degenerative and inflammatory changes of the lumbar region [> Modic III])

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Total final enrolment
80

Key exclusion criteria
1. Acute low back pain
2. Sciatica episodes
3. Degenerative changes of cervical or thoracic region (individuals with lesions I° and II° according to Modic classification will not be excluded from the study, only degeneration III° will be a basis for exclusion)
4. Past fractures of the bone structures of the spine; spinal surgery
5. Cancer
6. Vertebra forward dislocation
7. Rheumatoid arthritis and ankylosing spondylitis
8. Cauda equina syndrome
9. Pregnancy
10. Acute and chronic cardiovascular diseases
11. Arrhythmia and pacemaker
12. Metal implants
13. Dermatological conditions in the area of ESWT application
14. Sensory deficits
15. Psychiatric disorders

16. Immunological diseases
17. Infections
18. Chronic drug use
19. Problems with the balance system
20. Central nervous system diseases

Date of first enrolment
16/12/2019

Date of final enrolment
10/02/2020

Locations

Countries of recruitment
Poland

Study participating centre
Opole Medical School
68 Katowicka Street
Opole
Poland
45-060

Sponsor information

Organisation
Opole Medical School

Sponsor details
68 Katowicka Street
Opole
Poland
45-060
+48 (0)774423546
snw@wsm.opole.pl

Sponsor type
University/education

Website
http://wsm.opole.pl/15/4258/o-uczelni.html

ROR
https://ror.org/000bjk220

Funder(s)

Funder type
Not defined

Funder Name
Opole Medical School

Results and Publications

Publication and dissemination plan
Publications in peer-reviewed journals.

Intention to publish date
01/08/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (j.taradaj@awf.katowice.pl)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/06/2022	13/06/2022	Yes	No