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Focused shockwave and ultrasound therapies in the treatment of tennis elbow

Submission date
13/07/2020

Recruitment status
No longer recruiting

Registration date
30/07/2020

Overall study status
Completed

Last Edited
30/10/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims.
Lateral epicondylitis (tennis elbow) is a condition resulting from overuse and injury to the wrist and fingers following extension movements. Tennis elbow can have a range of symptoms, most commonly: pain in the lateral epicondyle (The bony bump on the outside of the elbow) that increases during extension of the wrist and fingers; tenderness of the lateral epicondyle when touched; and weakening of the wrist and finger muscles.

One form of therapy used to treat lateral epicondylitis involves mechanical waves such as ultrasound directed at the affected tendon. The aim of the trial is to determine the effects of focused shock wave and ultrasound therapies in the treatment of lateral epicondylitis.

Who can participate?
Patients with lateral epicondylitis.

What does the study involve?
Patients will be randomly divided into three equal groups A, B, and C. Group A will receive shock wave therapy once weekly over 3 weeks, group B will receive ultrasound therapy in 10 sessions over 2 weeks, while patients in group C will be treated with a false treatment that appears the same as group B but without the ultrasound. All patients will also be given deep friction massage.

What are the possible benefits and risks of participating?
Possible benefits of participating in the study include reduced pain, increased muscle strength, and an improvement in quality of life. Possible risks of participating in the study include local pain caused by deep friction massage and shock wave therapy.

Where is the study run from?
Academy of Physical Education in Katowice (Poland)

When is the study starting and how long is it expected to run for?
August 2020 to February 2022

Who is funding the study?
Academy of Physical Education in Katowice (Poland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2/2019

Study information

Scientific Title
The objective and subjective assessment of the effects of focused shockwave and ultrasound therapies in the treatment of lateral epicondylitis

Study objectives
1. Focused shockwave and ultrasound therapies have better effects than placebo ultrasound therapy
2. Focused shockwave therapy has better effects than ultrasound therapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/01/2019, the Research Ethics Committee of the Academy of Physical Education in Katowice (ul. Mikołowska 72, 40-065 Katowice, Poland; +48 322075152; a.smykla@awf.katowice.pl), ref: 2/2019

Study design
Single-centre interventional double-blinded randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Tennis elbow

Interventions

Patients with lateral epicondylitis will be enrolled in the trial. Patients will be randomly assigned to groups A, B and C, (1:1:1 ratio) in which participants will receive treatment with either focused shockwave therapy, ultrasound therapy, or sham ultrasound therapy, respectively.

Before the trial, the principal investigator will prepare a list with randomly arranged numbers, each denoting the group, which will be delivered to a physiotherapist in charge of treatment procedures. A physician will direct the enrolled patients to the person in charge of measurements and collecting the necessary data and then to the physiotherapist.

In group A, focused shockwave therapy will be delivered using the Richard Wolf Piezowave without local or general anaesthesia. A special cone-like cap focusing shock waves 5 mm from its top will be deployed. The site to be treated will be prepared by applying a special conductive gel before a procedure. Patients will be treated in a sitting position, with the affected arm abducted, the elbow joint flexed at approximately 60 degrees, and the forearm pronated and rested on the therapeutic table. Density energy will be set to 0.2 mJ/mm² and shock wave frequency to 4 Hz. During each procedure, 2,000 pulses will be applied to the most painful point of the lateral epicondylus. Patients will receive a total of three procedures separated by one week-interval, each lasting 8 min 20 sec.

Patients in group B will be treated with ultrasound generated by the Cosmogamma US13 EVO provided with a 5 cm² ultrasound applicator. The site to be treated will be prepared by applying a special conductive gel before a procedure. Patients will be treated in sitting position, with the affected the arm abducted, the elbow joint flexed at approximately 60 degrees, and the forearm pronated and rested on the therapeutic table. Ultrasound frequency will be set to 3 MHz and spatial average temporal peak (SATP) to 0.5 W/cm². The duty cycle will be 20%. During each procedure, the most painful point of the lateral epicondylus will be treated with ultrasound for 5 mins in a semi-stationary manner (the applicator's movements will be very limited). Patients will receive a total of 10 procedures on weekdays over two consecutive weeks.

The parameters of treatment in Groups A and B will be derived from clinical experience, reasoning, a literature review, and the general principles underlying the application of physical modalities.

Patients in group C will also be treated using the Cosmogamma US13 EVO unit. Their position during treatment and the unit's settings will also be the same apart. The only difference will be that the applicator will not generate ultrasound. Patients will receive a total of 10 procedures on weekdays over two consecutive weeks.

In all three groups, shockwave and ultrasound therapies will be combined with a deep friction massage. Patients will be massaged while sitting with the arm slightly flexed, the elbow joint bent at approximately 70 degrees, and the forearm in a mid-position between supination and pronation. The massage procedures will last 12 min and will be held every second day during the treatment period (excluding the weekend), so each patient will receive a total of 7 procedures. Each procedure will be carried out 30 mins before shock wave or ultrasound therapies. In performing the massage, the therapist will use the index finger with the middle finger placed on it to increase pressure, making sure that it is strong but tolerable. The frequency of movements will be 2-3 Hz. A transverse friction technique will be used (pressure will be applied when the fingers are moving forward and released on return).
All procedures will be carried out by a long-experienced physiotherapist.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
1. Richard Wolf Piezowave 2. Cosmogamma US13 EVO

Primary outcome measure
1. Grip strength in the affected and unaffected upper limbs measured by a SH5001 dynamometer (SAEHAN Corporation) at baseline, 1, 6 and 12 weeks
2. Strength of the wrist extensors in the affected and unaffected upper limbs measured by a SH5001 dynamometer (SAEHAN Corporation) at baseline, 1, 6 and 12 weeks
3. Strength of the wrist flexors in the affected and unaffected upper limbs measured by a SH5001 dynamometer (SAEHAN Corporation) at baseline, 1, 6 and 12 weeks
4. Pain intensity during physical activity measured on the Visual Analog Scale 0-10 (VAS) at baseline, 1, 6 and 12 weeks
5. Pain intensity at rest measured on the Visual Analog Scale 0-10 (VAS) at baseline, 1, 6 and 12 weeks
6. Pain intensity at night measured on the Visual Analog Scale 0-10 (VAS) at baseline, 1, 6 and 12 weeks

Secondary outcome measures
1. Quantitative pain assessment performed with the modified Laitinen’s questionnaire at baseline, 1, 6 and 12 weeks
Quantitative pain assessment will be performed pre-treatment and at weeks 1, 6, and 12 post-treatment.
2. Pain intensity and difficulty in performing daily activities measured using the Patient-Rated Tennis Elbow Evaluation (PRTEE) at baseline, 1, 6 and 12 weeks
3. The extent of disability of the affected upper limb measured using the Disabilities of the Arm, Shoulder and Hand questionnaire (DASH) at baseline, 1, 6 and 12 weeks
4. Treatment outcomes assessed based on the Roles and Maudsley score (RMS) at 1, 6, and 12 weeks

Overall study start date
15/10/2018

Completion date
04/02/2022

Eligibility

Key inclusion criteria
1. Pain in the lateral epicondyle persisting for ≥3 months
2. Pain on palpation in the lateral epicondyle
3. A positive Thompson’s test (the patient reports pain when performing resisted extension of a slightly extended wrist, with the fingers clenched into a fist, the elbow extended, and the forearm in a pronated position)
4. A positive Mill’s test (the patient reports pain when performing resisted supination of the forearm with the elbow joint slightly flexed, the forearm in a pronated position, the wrist

slightly extended, and the fingers clenched into a fist)
5. Pain during resisted extension of the middle finger
6. Aged 18 to 65 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60 (20 in each group)

Total final enrolment
60

Key exclusion criteria
1. Local infection
2. Pregnancy
3. Malignancy
4. Bilateral tennis elbow
5. Carpal tunnel syndrome
6. Medial epicondylitis
7. Elbow arthritis or instability
8. Generalized polyarthritis
9. Ipsilateral shoulder dysfunction
10. Neurological abnormalities
11. Radial-nerve entrapment
12. Cardiac arrhythmia or a pacemaker
13. Diabetes
14. Physical therapy and/or a corticosteroid injection administered within the previous six weeks

Date of first enrolment
03/08/2020

Date of final enrolment
22/10/2021

Locations

Countries of recruitment
Poland

Study participating centre
OSTEOMED - Centrum Osteopatii i Fizjoterapii (Osteopathy and Physiotherapy Centre)
ul. Południowa 18
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Poland
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Sponsor information

Organisation
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Sponsor type
University/education

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Funder(s)

Funder type
University/education

Funder Name
Academy of Physical Education in Katowice

Results and Publications

Publication and dissemination plan
PhD dissertation

Intention to publish date
01/10/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to ethics restriction on sharing data.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (other)	protocol (not peer reviewed)		17/08/2021	No	No
Basic results			03/11/2023	No	No
Results article		30/10/2024	30/10/2024	Yes	No