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TECAR therapy in the treatment of tennis elbow

Submission date
19/07/2020

Recruitment status
No longer recruiting

Registration date
04/08/2020

Overall study status
Completed

Last Edited
17/08/2021

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.
Lateral epicondylitis (also known as tennis elbow) is one of the most common conditions affecting the upper limbs. It involves pain in the lateral epicondylus (a small bump on the outside of the elbow) that tends to increase during resisted extension of the wrist and fingers, tenderness of the lateral epicondyle on palpation, and weakening of the wrist and finger extensors.

One of the physical therapies used to treat lateral epicondylitis is called TECAR therapy. TECAR therapy is a form of combined contact diathermy and electrotherapy. It uses electromagnetic energy to apply heat to the affected area but unlike electrotherapy, it does not provoke muscle contraction. The trial is aimed to assess the effects of TECAR therapy in the treatment of lateral epicondylitis.

Who can participate?
Adult patients with lateral epicondylitis.

What does the study involve?
The patients will be divided randomly into two groups, which will receive either TECAR or sham TECAR treatment respectively. In both groups, therapy will be combined with 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 skin burn caused by TECAR.

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?
November 2018 to February 2022

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

Who is the main contact?
Piotr Król
p.krol@awf.katowice.pl

Contact information

Type(s)
Scientific

Contact name
Dr Piotr Król

ORCID ID
https://orcid.org/0000-0001-7673-4375

Contact details
ul. Mikołowska 72b
Katowice
Poland
40-065
+48 606 62 89 89
p.krol@awf.katowice.pl

Additional identifiers

Protocol serial number
2/2019

Study information

Scientific Title
An objective and subjective assessment of the effects of TECAR therapy in the treatment of lateral epicondylitis

Study objectives
TECAR therapy has better effects than placebo TECAR 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.

Primary study design
Interventional

Study design

Single-centre interventional double-blinded randomized control trial.

Study type(s)
Treatment

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

Interventions
The trial participants will be patients with lateral epicondylitis. They will be randomly divided between comparative groups A and B, which will receive TECAR therapy and sham TECAR 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.

TECAR therapy in group A will be delivered using the WINBACK BACK 1s device. Participants will be treated in a sitting position. A treatment session will start with a conductive cream being applied to the site to be worked on. To the bottom of the patient's affected forearm, a large resistive electrode closing the circuit will be attached. Each session will be consists of three 5-min procedures, so the total treatment time will be 15 min. During the first procedure, the lateral epicondylus, the common tendon, and the bellies of the wrist and finger extensors will be treated with a small capacitive electrode. The intensity of the electromagnetic field will be set to produce a pleasant feeling of warmth in the treated tissues (120-200 [VA]). During the second procedure, the site where the common tendon of the wrist extensors and fingers attaches to the lateral epicondylus will be worked on with a small resistive electrode. The intensity of the electromagnetic field will be changed to produce an intense feeling of warmth (30-50 [W]). The third procedure will focus again on the site where the common tendon of the wrist extensors and fingers attaches to the lateral epicondylus. This time the physiotherapist will wear a special bracelet-like resistive electrode on the forearm which will cause intense overheating of tissues (30-50 [W]) via the physiotherapist's fingers performing deep friction massage across the most painful site. Each patient will receive three treatments over a period of one week, i.e. 9 procedures in total.
Sham TECAR therapy in group B will be delivered using the same device and according to the same protocol. The only difference will be that BACK 1s will not generate electromagnetic waves.
In both groups, TECAR therapy 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 for 12 min. 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 9 procedures. Each procedure will be carried out 30 min before TECAR therapy. 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 an experienced physiotherapist.

Intervention Type

Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
WINBACK BACK 1s

Primary outcome(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
10/08/2020

Date of final enrolment
22/10/2021

Locations

Countries of recruitment
Poland

Study participating centre
Physiotherapy Centre: FIZJOTERAPIA-KRÓL DR HAB. PIOTR KRÓL
ul. Łabędzia 17
Katowice
Poland
40-521

Sponsor information

Organisation
Academy of Physical Education in Katowice

Funder(s)

Funder type
University/education

Funder Name
Academy of Physical Education in Katowice

Results and Publications

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