ISRCTN17001174 https://doi.org/10.1186/ISRCTN17001174

Laser or pulsed electromagnetic field: which treatment is more effective for knee osteoarthritis?

Submission date
06/04/2022

Recruitment status
No longer recruiting

Registration date
20/04/2022

Overall study status
Completed

Last Edited
17/03/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aim
Knee osteoarthritis (KOA) causes the cartilage in the knee joint to thin and the surfaces of the joint to become rougher so the knee doesn't move as smoothly as it should and might feel painful and stiff. Low-level laser therapy (LLLT) and pulsed electromagnetic field laser therapy (PEMF) are effective and non-invasive treatments for KOA. In this study, patients with KOA will receive either PEMF or LLLT to see which treatment is more effective for KOA in terms of pain relief and improved function.

Who can participate?
Men and women older than 50 years old and up to 75 years old with symptomatic knee pain lasting for 6 months or longer. Patients must be able to walk for at least 30 meters.

What does the study involve?
Participants will be randomly allocated to one of two groups. One group will receive PEMF treatment and the other will receive LLLT treatment sessions. The treatment modalities will be delivered by trained physiotherapists. The treatment will be performed lying face upwards with the headrest raised according to the patient's comfort, and the knee supported on a pillow at about 15-30 degrees flexion (bending), depending on the comfort and pain reported by the patient. Each treatment is composed of six sessions, twice a week.

What are the possible benefits and risks of participating?
The possible benefits are decreased pain and increased ability to walk and function. There are no known risks to participants.

Where is the study run from?
Nedica Physical Therapy Clinic (Israel)

When is the study starting and how long is it expected to run for?
February 2021 to October 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Michal Elboim-Gabyzon
michal.elboim@gmail.com
moelboum-@staff.haifa.ac.il

Contact information

Type(s)
Principal Investigator

Contact name
Dr Michal Elboim-Gabyzon

ORCID ID
http://orcid.org/0000-0002-7278-9421

Contact details
199 Aba Khoushy Ave., Mt. Carmel
Haifa
Israel
3498838
+972 (0)545968943
moelboum-@staff.haifa.ac.il

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
08051928

Study information

Scientific Title
Laser or pulsed electromagnetic field: which modality is more effective in the treatment of knee osteoarthritis? A randomized controlled trial

Study objectives

It is hypothesized that both therapies modalities would cause a decrease in pain intensity and an increase in the level of function in subjects with knee osteoarthritis (KOA). Yet, it is not possible to determine whether a difference would be found between the modalities

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/01/2022, Ethical Review Board, Faculty of Social Welfare and Health Sciences at the University of Haifa (199 Aba Khoushy Ave. Mount Carmel, Haifa, Israel; +972 (0)4 8249948 (internal: 53948); pfientu1@univ.haifa.ac.il), ref: 069/21

Study design
Single-center double-blind randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Primary knee osteoarthritis

Interventions
Participants are randomly assigned to one of the two intervention groups by using a computer-generated random software sequence of allocation. Participants are randomized by the clinic secretary, who was not involved in the study, prior to the pre-intervention assessment once the eligibility criteria are confirmed.

The low-level laser therapy (LLLT) intervention is carried out while wearing goggles, which are one of the system's accessories. LLLT is applied in a six-session format twice a week. The treatment parameters are: power 100%, dose 8 J/cm², frequency 2 Hz, duty factor 75%, treatment area 20 cm² applied over five points over the anterior part of the articular space, for 3 minutes for each point for a total time of 15 minutes.

The pulsed electromagnetic field laser therapy (PEMF) applicator is applied over the medial and lateral side of the knee. The parameters are field shape rectangular, frequency 30 Hz, intensity 10 mT, treatment time 15 minutes. Each treatment modality is composed of six sessions, twice a week.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain intensity during rest, walking, and while standing up measured using the visual analog scale (VAS) at baseline and post the six sessions (week 3)

Secondary outcome measures
1. Pain intensity, stiffness, and level of physical functioning measured using the Hebrew version of the Western Ontario and McMaster Universities Osteoarthritis questionnaire (WOMAC) at baseline and post the six sessions (week 3)
2. Functional mobility measured using the Timed Up and Go (TUG) test at baseline and post the six sessions (week 3)
3. Walking ability measured using the 10-Meter Walk (10MW) at baseline and post the six sessions (week 3)

Overall study start date
01/02/2021

Completion date
15/10/2021

Eligibility

Key inclusion criteria
1. Primary KOA
2. Age 50-75 years old
3. Both genders
4. Symptomatic knee pain lasting for 6 months or longer
5. Pain level ≥4 out of 10 according to the Visual Analog Scale (VAS scale)
6. Independent walking ability of at least 30 meters
7. KOA level of 2-3 according to the Kellgren–Lawrence classification scale

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
46

Total final enrolment
40

Key exclusion criteria

1. Participants with secondary KOA
2. Significant sensory disturbances in the lower extremities
3. Uncontrolled diabetes or uncontrolled heart disease
4. Body Mass Index (BMI) >40 kg/m²
5. Presence of pacemaker
6. Previous surgeries in lower limbs
7. Metal or implants in the body
8. Inability to understand simple instructions

Date of first enrolment
15/05/2021

Date of final enrolment
15/09/2021

Locations

Countries of recruitment
Israel

Study participating centre
Nedica Clinic
Road 500 / A Sheikh Amin Tarif Shefar'am 151
Shefar'am
Israel
2020000

Sponsor information

Organisation
University of Haifa

Sponsor details
199 Aba Khoushy Ave.
Mt. Carmel
Haifa
Israel
3498838
+972 (0)4 8249278 (internal: 53278)
szalka@univ.haifa.ac.il

Sponsor type
University/education

Website

http://www.haifa.ac.il/index.php/en/

ROR
https://ror.org/02f009v59

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/06/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Michal Elboim-Gabyzon (michal.elboim@gmail.com, moelboum-@staff.haifa.ac.il). Each request will be discussed specifically considering ethical or legal restrictions.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	outcome results	16/03/2023	17/03/2023	Yes	No