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

Submission date	Recruitment status	Prospectively registered
06/04/2022	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
20/04/2022	Completed	[X] Results
Last Edited	Condition category	Individual participant data
17/03/2023	Musculoskeletal Diseases	

## 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**

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## Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## Study type(s)

Treatment

## 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 computergenerated 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(s)

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)

## Key secondary outcome(s))

- 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)

## 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** 

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

ΔII

## 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/m<sup>2</sup>
- 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

#### **ROR**

https://ror.org/02f009v59

# Funder(s)

# Funder type

Other

## **Funder Name**

Investigator initiated and funded

## **Results and Publications**

## 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 outcome results

Date created Date added Peer reviewed? Patient-facing?

16/03/2023 17/03/2023 Yes