

Can regenerative photonic therapy improve pain and mobility in knee osteoarthritis?

Submission date 21/10/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 08/11/2013	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 08/11/2013	Condition category Musculoskeletal Diseases	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

We are carrying out a study of 60 participants with radiologically confirmed knee osteoarthritis (OA) to investigate if Regenerative Photonic Therapy (RPT) plus exercises is more effective for walking pain and mobility as compared to placebo (dummy) RPT and exercises. Exercises were proven in previous clinical studies to be beneficial for knee OA symptoms. RPT is a physiotherapy treatment that utilizes special forms of monochromatic light and laser therapy with a goal to reduce pain and inflammation and improve mobility. RPT is an advancement of a treatment known as low level laser therapy (LLLT). Both RPT and LLLT were shown in previous studies to be beneficial for pain relief in knee OA. This study aims to find out whether RPT plus exercises is more effective for walking pain relief and mobility improvement than dummy RPT plus exercises.

Who can participate?

Patients who are 50-85 years old and suffering from chronic (more than 6 months duration) knee osteoarthritis pain.

What does the study involve?

All eligible participants will be randomly allocated to one of two treatment groups. One group of participants will receive RPT plus exercises and the other group will receive dummy RPT plus exercises for 6 weeks. Participants of the study will visit the clinic 14 times for 1-2 hours per visit to receive treatment and to be examined. The treatments will be provided by registered physiotherapists and their assistants under the physiotherapists supervision. At the end of the study, we will compare if RPT was beneficial for improving walking pain and mobility after completion of the treatment program and at 1 and 6 months follow-up visits.

What are the possible benefits and risks of participating?

Previous research suggests that participants with knee OA undergoing the treatment program may benefit from fast pain relief after treatment and lasting up to 6 months, function and mobility improvement, reduction of pain medication, and improvement of sleep at night. All participants (both RPT and dummy RPT) are expected to benefit from treatment as all participants will receive exercise therapy that was proven to be beneficial in numerous studies. RPT and LLLT are considered to be low-risk treatments. There have been no side effects

reported from using these treatments since their first use in the 1970s. The laser used in the study has a potential risk for eye damage which is eliminated using special protective glasses.

Where is the study run from?

This study has been set up by Seneca College of Applied Arts and Technology, Canada.

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

The study recruitment started in October 2012 and the study is expected to be completed in November 2013.

Who is funding the study?

Funding has been provided by the Federal Development Agency for Ontario, International Medical Instruments Inc. and Seneca College of Applied Arts and Technology, Canada.

Who is the main contact?

Professor Caroline E Grammer

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Contact information

Type(s)

Scientific

Contact name

Prof Caroline Grammer

Contact details

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Additional identifiers

Protocol serial number

12-26

Study information

Scientific Title

Efficacy of regenerative photonic therapy (RPT) plus exercises versus exercises for the treatment of knee osteoarthritis in geriatric care: a randomized placebo-controlled clinical trial

Acronym

KOAS

Study objectives

Regenerative photonic therapy (RPT) plus exercise is more effective than placebo RPT and exercise for the relief of walking pain and improvement of performing daily activities in patients with knee osteoarthritis.

More details can be found at:

1. <http://www.carp.ca/2012/09/21/torontos-seneca-college-study-on-zoomer-knee-pain-participants-needed/>
2. <http://www.canhealth.com/tfdnews0660.html>

Ethics approval required

Old ethics approval format

Ethics approval(s)

Office of Research & Innovation, Research Ethics Board of Seneca College of Applied Arts and Technologies, 31/08/2012, Ref. File # 12-26

Primary study design

Interventional

Study design

Prospective randomized placebo-controlled double-blinded clinical study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Knee osteoarthritis

Interventions

The treatment group will receive regenerative photonic therapy (RPT) plus exercises while the control group will receive placebo (dummy) RPT and exercises.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Western Ontario and McMaster Universities Arthritis Index (WOMAC) subscale difficulties performing daily activities (DPDA)
2. Walking pain by Visual Analog Scale (VAS, 0 = no pain, 10 = worst possible pain)

Primary outcomes will be measured upon completion of 6 weeks treatment, at one month and six months follow-up.

Key secondary outcome(s)

1. WOMAC Total
2. WOMAC Pain subscale
3. The highest weekly pain by Visual Analog Scale (VAS, 0 = no pain, 10 = worst possible pain)
4. Pain medication intake (amount of pain pills per day)

Secondary outcomes will be measured upon completion of 6 weeks treatment, at one month and six months follow-up.

Completion date

30/11/2013

Eligibility

Key inclusion criteria

1. Patients aged 50-85 years old
2. Patients suffering from chronic (more than 6 months duration) knee osteoarthritis (OA) pain
3. Able to provide informed consent in a written form

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Surgical joint replacement
2. Radiological grade 1 and 4 osteoarthritis
3. Oral opioid or steroid medications
4. Recent (< 1 month) knee injection
5. Leg fractures
6. Fibromyalgia
7. Polyarthritis
8. Severe cardiovascular disease
9. Recent myocardial infarction or stroke (<1 year)
10. Pacemaker
11. Malignancy
12. Epilepsy
13. Pregnancy
14. Acute viral or bacterial infection
15. HIV
16. Uncontrolled diabetes (blood glucose > 11, or glucose in urine)
17. Neurological manifestations (numbness, paraesthesia, loss of sensitivity anywhere in the body)
18. Known autoimmune diseases (e.g., lupus, rheumatoid arthritis)

Date of first enrolment

01/10/2012

Date of final enrolment

30/11/2013

Locations

Countries of recruitment

Canada

Study participating centre

Seneca College,
Markham, Ontario
Canada
L3R 5Y1

Sponsor information

Organisation

International Medical Instruments Inc. (Canada)

Funder(s)

Funder type

Industry

Funder Name

FedDev Ontario (Canada)

Funder Name

International Medical Instruments Inc. (Canada)

Funder Name

Seneca College of Applied Arts and Technology (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration