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

Submission date
21/10/2013

Recruitment status
No longer recruiting

Registration date
08/11/2013

Overall study status
Completed

Last Edited
08/11/2013

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Prospective randomized placebo-controlled double-blinded clinical study

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 the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/10/2012

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

Age group
Senior

Sex
Both

Target number of participants
60

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)

Sponsor details
1600 Steeles Avenue West
Unit 21
Concord, Ontario
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L4K 4M2

Sponsor type

Industry

Website
http://www.imihealingtechnologies.com

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration