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Clinical effects of radiofrequency based therapy

Submission date
23/04/2015

Recruitment status
No longer recruiting

Registration date
13/05/2015

Overall study status
Completed

Last Edited
02/09/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA), the most common type of arthritis, is a condition that causes joints to become painful and stiff. OA typically affects the knees, hips and small joints of the hands. OA is an incurable, long term condition but there are a number of ways to improve symptoms, such as maintaining a healthy weight and regularly exercising. Unfortunately, OA of the knee can often result in disability and make it hard for people to carry out their normal daily activities. It can also make it difficult for people to exercise. Physiotherapists can help people put together an exercise plan to manage their symptoms. They can also provide various treatments to reduce pain and swelling in the joints, such as radiofrequency (RF) therapy. RF therapy generates heat in the tissues of the affected area, which increases blood flow and relieves pain and inflammation. The standard RF therapy given to patients is shortwave therapy, which delivers a 27.12 Megahertz frequency to the affected joint. There are various types of devices available, including ones that operate at very low frequencies (below 1 Megahertz), although it is not clear how well they actually work. Capacitive Resistive Monopolar Radiofrequency (CRMRF) (448 Kilohertz) is one such low frequency device. The aim of this study is to see how well CRMRF therapy works to relieve pain and improve quality of life in patients suffering from chronic OA of the knee compared to standard therapy. CRMRF will be delivered using the Indiba Activ 902 device.

Who can participate?
Adults diagnosed with OA of the knee.

What does the study involve?
Participants are randomly allocated into one of three groups. Those in group 1 (intervention group) receive CRMRF therapy alongside standard RF therapy. Those in group 2 (placebo group) receive ‘dummy’ CRMRF therapy alongside standard RF therapy. Those in group 3 (control group) receive standard care only. All participants receive treatment twice a week for four weeks. Participants are assessed for pain and quality of life using questionnaires before, immediately after, and one and three months following treatment. Participants take part in the study for a total of four months.

What are the possible benefits and risks of participating?
The results will help identify whether adding CRMRF to the current care provides any 'added value', and also whether it provides better results than an equivalent placebo treatment. The study will also provide useful data for further research.

Where is the study run from?
Hertfordshire Community NHS Trust (UK)

When is the study starting and how long is it expected to run for?
May 2015 to February 2016

Who is funding the study?
INDIBA SA (Spain)

Who is the main contact?
1. Prof T Watson (public)
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2. Mr B Kumaran (scientific)
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HSK/PG/NHS/00312

Study information

Scientific Title
Clinical effects of 448 KHz capacitive resistive monopolar radiofrequency (CRMRF) based therapy on patients suffering from chronic osteoarthritis of the knee joint

Study objectives
The capacitive resistive monopolar radiofrequency (CRMRF) therapy has a statistically and clinically significant benefit over current standard care as well as a placebo-CRMRF intervention in terms of patient and clinical outcomes among patients suffering from chronic osteoarthritis of the knee joint.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Greater Manchester South, 25/06/2015, ref: 15/NW/0529

Study design
Single-centre single-blind prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Osteoarthritis (OA) of the knee joint

Interventions
1. Group A (treatment): CRMRF therapy + current standard treatment twice a week for 4 weeks
2. Group B (placebo): CRMRF therapy + current standard treatment twice a week for 4 weeks
3. Group C (control): current standard treatment only

Intervention Type
Device

Primary outcome measure
Assessed at baseline, immediately after treatment, then again 1 and 3 months following intervention:
1. Visual Analogue Scale (VAS) for pain
2. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) for functional quality of life (QoL)

Secondary outcome measures
1. Knee joint range of motion
2. 'Timed up and go' test
3. Skin temperature (physiological)
4. Skin blood flow (physiological)
5. Muscle blood flow (physiological)

Overall study start date
01/05/2015

Completion date
31/10/2016

Eligibility

Key inclusion criteria
1. Clinical and radiological diagnosis of OA knee
2. Pain and symptoms in the knee for at least three months
3. Over 18 years of age

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

Total final enrolment
45

Key exclusion criteria
1. Significant underlying medical conditions
2. OA of other joints such as hip or ankle
3. Currently receiving/received (in the last six months) treatment (including invasive procedures) other than standard care
4. Inability to consent

Date of first enrolment
15/06/2015

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hertfordshire Community NHS Trust
Welwyn Garden City
United Kingdom
AL7 1BW

Sponsor information

Organisation
University of Hertfordshire

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Sponsor type

University/education

Website
http://www.herts.ac.uk/

ROR
https://ror.org/0267vjk41

Funder(s)

Funder type
Industry

Funder Name
INDIBA SA (Spain)

Results and Publications

Publication and dissemination plan
We aim to publish the results in a leading international journal.

Intention to publish date
31/01/2017

Individual participant data (IPD) sharing plan
Participant level data is subject to commercial embargo, hence the researchers are unable to share it.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2019	02/09/2020	Yes	No
HRA research summary			28/06/2023	No	No