

Clinical effects of radiofrequency based therapy

Submission date 23/04/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/05/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/09/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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)

t.watson@herts.ac.uk

2. Mr B Kumaran (scientific)

b.r.kumaran@herts.ac.uk

Contact information

Type(s)

Public

Contact name

Mr Tim Watson

Contact details

Physiotherapy, Department of Allied Health Professions and Midwifery

School of Health and Social Work, University of Hertfordshire

College Lane, Hatfield

United Kingdom

AL10 9AB

+44 (0)1707 284000

t.watson@herts.ac.uk

Type(s)

Scientific

Contact name

Mr Binoy Kumaran

Contact details

44a Grove Road

Luton

United Kingdom

LU1 1QJ

+44 (0)7517430077

b.r.kumaran@herts.ac.uk

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

Sponsor details

Physiotherapy, Department of Allied Health Professions and Midwifery

School of Health and Social Work, University of Hertfordshire

Hatfield

England

United Kingdom

AL10 9AB

+44 (0)1707 284000

ask@herts.ac.uk

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