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Intrasound therapy and transcutaneous electrical nerve stimulation (TENS) in the treatment of osteoarthritis of the knee

Submission date
28/03/2015

Recruitment status
No longer recruiting

Registration date
16/06/2015

Overall study status
Completed

Last Edited
12/05/2015

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
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 treatments available to manage its symptoms, in addition to maintaining a healthy weight and regularly exercising. 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 to create an exercise plan to manage their symptoms. They also provide various treatments to reduce pain and swelling in the joints. One such treatment is transcutaneous electrical nerve stimulation (TENS), which is often used to reduce pain in OA. In TENS, electrodes attached to a small, battery-operated machine are placed on the affected body part, such as the knee. When the machine is switched on, electrical signals are sent to the nerves which disrupt the pain signals. There are also various complementary and alternative therapies available to people with OA. Intrasound Therapy (IST) is a complementary therapy which uses sound waves to give pain relief for inflammatory conditions such as OA of the knee. It is a simple device for home use, and some OA sufferers have found that it helps relieve their symptoms. However, IST has not been scientifically tested so we don't know how well it actually works. This is the first study to test how well IST works in adults with OA of the knee. The aim of this study is to see how well IST works to help patients with OA of the knee manage their pain compared to TENS.

Who can participate?
Adult with OA of the knee

What does the study involve?
Participants are randomly allocated into one of three groups. Those in group 1 (control group) carry out a range of exercises. Those in group 2 (intervention group) receive IST and carry out a range of exercises. Those in group 3 (intervention group) receive TENS and carry out a range of exercises. Mobility and pain levels are measured before treatment and after 8 weeks of treatment. Participants also complete questionnaires.

What are the possible benefits and risks of participating?
Participants are not exposed to any known risks as the treatments are considered safe to use.

Where is the study run from?
Lagos University Teaching Hospital (Nigeria)

When is the study starting and how long is it expected to run for?
June 2014 to November 2014

Who is funding the study?
Investigator initiated and funded (Nigeria)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Intrasound therapy is an effective adjunct in the management of osteoarthritis of the knee: a preliminary clinical study

Study objectives
Will intrasound therapy be as effective as TENS, a proven physiotherapy modality as an adjunct in the management of osteoarthritis of the knee?

Ethics approval required
Old ethics approval format

Ethics approval(s)

Health, Research and Ethics Committee of the Lagos University Teaching Hospital, Nigeria, 22/07/2014, ref: ADM/DCST/HREC/1806

Primary study design
Interventional

Study design
Single-centre preliminary clinical interventional study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild/moderate unilateral osteoarthritis of the knee

Interventions
1. Group 1 (control): closed kinetic chain exercises and range of motion exercises
2. Group 2 (intervention): intrasound therapy for 10 minutes followed by closed kinetic chain exercises and range of motion exercises
3. Group 3 (intervention): TENS for 15 minutes followed by closed kinetic chain exercises and range of motion exercises

Intervention Type
Device

Primary outcome(s)
Assessed pre-treatment, at baseline and post-treatment after 8 weeks of intervention: Western Ontario and McMaster Universities (WOMAC) score to assess pain, stiffness and physical function.

Key secondary outcome(s)
Assessed pre-treatment, at baseline and post-treatment after 8 weeks of intervention:
1. 6-minute walk test
2. Range of motion of the knee

Completion date
14/11/2014

Eligibility

Key inclusion criteria
1. Age 52-76
2. Unilateral OA of the knee

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with underlying systemic diseases and other rheumatic conditions of the knee
2. Patients with severe OA using the Kellgren and Lawrence system of classification

Date of first enrolment
29/07/2014

Date of final enrolment
12/09/2014

Locations

Countries of recruitment
Nigeria

Study participating centre
Lagos University Teaching Hospital
Department of physiotherapy
Lagos
Nigeria

Sponsor information

Organisation
Lagos University Teaching Hospital

ROR
https://ror.org/00gkd5869

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request