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Electrical nerve stimulation on perceived knee pain and gait characteristics

Submission date
19/11/2015

Recruitment status
No longer recruiting

Registration date
02/12/2015

Overall study status
Completed

Last Edited
07/01/2022

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The knee is the largest weight-bearing joint in the body. It is a complex joint where the shin bone (tibia) and thigh bone (femur) meet creating a “hinge”. One of the most common causes of knee pain is Osteoarthritis (OA). This occurs when the protective cartilage on the end of bones wears away. The bones then rub against one another, causing stiffness, pain and a reduction in the range of movement, causing abnormal gait (instability while walking). The primary aim of healthcare professionals treating patients with knee pain is to relieve pain and help people to recover their normal range of movement. A transcutaneous electrical nerve stimulation (TENS) machine is a device designed to provide pain relief using electrical stimulation. It is attached to sticky pads (electrodes) which are placed on the skin around the area where pain is felt. Small electrical pulses are then delivered to the body through these electrodes, which can help to ease pain by affecting the way that nerves send pain signals to the brain. Studies have shown that TENS can help to relieve pain and restore movement in a number of conditions. More evidence is needed to find out if it can help to restore abnormal gait due to knee pain however. The aim of this study is to find out if TENS treatment is an effective way of reducing pain and restoring normal gait in experimental knee pain (knee pain which is created for the purpose of the study).

Who can participate?
Health adults aged between 18 and 45 who take part in regular exercise.

What does the study involve?
Participants attend three study visits in order to cause knee pain for the experiment. In the first visit, hypertonic saline solution (salt water which is more concentrated than in the blood) is injected into the space surrounding the knee joint. In the second and third visits, isotonic saline solution (salt water with the same salt concentration as the blood) and water are used in order to show the specific effects caused by the hypertonic solution. After the experimental knee pain sessions, participants are randomly allocated to one of two groups. Those in the first group are connected to a TENS machine using electrodes, which are evenly spaced around the knee. The machine then delivers continual electrical pulses to the knee for 20 minutes. Those in the second group are connected to a placebo (dummy) device which is not designed to have any pain-

relieving effects for 20 minutes. At the start of the study, during the infusion and after the treatment, participants in both groups are asked to rate their level of pain on a scale of 1-10, and have are filmed walking so that their gait (manner of walking) can be analysed.

What are the possible benefits and risks of participating?
There are no direct benefits of taking part in this study. Participants are expected to experience pain and discomfort during the infusion however these affects will wear off quickly.

Where is the study run from?
Brigham Young University (USA)

When is the study starting and how long is it expected to run for?
August 2013 to December 2013

Who is funding the study?
Brigham Young University (USA)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

F130284

Study information

Scientific Title
Effects of transcutaneous electrical nerve stimulation on perceived knee pain and gait characteristics in individuals with experimental knee pain

Study objectives
1. Experimental knee pain would result in altered gait characteristics during various portions of stance
2. Compared to placebo treatment, TENS treatment would reduce perceived knee pain and restore gait characteristics that were altered due to experimental knee pain

Ethics approval required
Old ethics approval format

Ethics approval(s)
Brigham Young University's Institutional Review Board for Human Subjects, 15/08/2013, ref: F130284

Study design
Single-center controlled cross-over laboratory intervention trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
School

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 pain

Interventions
Participants are randomly allocated to one of two groups. During the study, participants are required to participate in at least 90 min/week of cardiovascular, resistance and/or other sport-related physical activity, and are not allowed to do strenuous exercise or take any analgesic/anti-inflammatory medication 24 hours before data collection.

Participants are then given 3 separate experimental knee pain sessions which involve hypertonic saline infusion, isotonic saline infusion, and control. Regarding experimental knee pain procedures, after prepping the skin with an alcohol wipe and iodine, a 20-gauge flexible catheter was inserted into the right infrapatellar fat pad. A 30-ml syringe, connected to the catheter, was attached to a portable infusion pump, which produced a continuous saline flow of 0.154 ml/min for 50 minutes (7.7 ml) into the fat pad. Isotonic saline infusion was used for the sham session, allowing us to differentiate potential mechanical effects (catheter insertion and fluid pressure) from effects of the hypertonic saline infusion (pain session). No catheter was involved in the control session. After the infusion initiation, subjects lay supine for three minutes, sat upright for three minutes, and stood for two minutes, so that the subjects could become familiar with the saline infusion effects. Subjects were required to lie, sit, and stand for equivalent time during a control session to maintain consistency over all three experimental data collection sessions.

TENS Group: Following the experimental knee pain sessions, self-adhesive square electrodes are placed around the borders of the patella with approximately 5 to 7 cm distance between them. The TENS device then delivers continuous (normal mode) asymmetric biphasic square-pulse wave with a pulse width of 120 microseconds and a pulse rate of 180 Hz. Electrical stimulation intensity is increased until a visible contraction of the vastus medialis is seen, and then manually decreased until no contraction is seen or felt by the investigator. The treatment lasts for 20 minutes, while the patient is in a seated upright position.

Placebo Group: Following the experimental knee pain sessions, participants are attached to a placebo device not designed to provide significant electrical stimulation. The treatment lasts for 20 minutes, while the patient is in a seated upright position.

Intervention Type
Device

Primary outcome measure
1. Perceived knee pain is measured using a visual analogue scale (VAS) at baseline and every two minutes throughout the study
2. Gait characteristics (joint angle and torque) are measured using high-speed video and a force plate with 59 reflective markers at baseline (0 minute), infusion (8 minutes), and treatment (38 minutes)

Secondary outcome measures
1. Perceived knee pain is measured using a visual analogue scale (VAS) under hypertonic saline infusion
2. Gait characteristics (joint angle and torque) are measured using high-speed video and a force plate with 59 reflective markers under hypertonic saline infusion

Overall study start date
15/08/2013

Completion date
15/12/2013

Eligibility

Key inclusion criteria

1. Aged between 18 and 45 years
2. Participating in at least 90 minutes/week and 3 days/week of sport-related weight-bearing physical activity

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. History of cardiovascular, resistance and/or other sport-related physical activity (at least 90 min/week and 3 days/week in the past 3 months)
2. History of lower-extremity orthopedic surgery, fracture, or neurological disorders in their lifetime
3. History of sport-related lower extremity orthopedic injury in the past 6 months

Date of first enrolment
15/08/2013

Date of final enrolment
15/09/2013

Locations

Countries of recruitment
United States of America

Study participating centre
Human Performance Research Center at Brigham Young University
Human Performance Research Center
116 Richards Building
Provo
United States of America
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Sponsor information

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Brigham Young University

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Sponsor type
University/education

ROR
https://ror.org/047rhhm47

Funder(s)

Funder type
University/education

Funder Name
Brigham Young University

Results and Publications

Publication and dissemination plan
Planned publication in Arthritis Research and Therapy journal.

Intention to publish date
29/02/2016

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/06/2016	07/01/2022	Yes	No