The effects of patellar tape on neural correlates during knee joint proprioception tests using fMRI: a pilot study

Submission date	Recruitment status	[] Prosp
29/09/2006	No longer recruiting	[] Proto
Registration date 29/09/2006	Overall study status Completed	[] Statis
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Last Edited 09/08/2021	Condition category Musculoskeletal Diseases	[] Indivi

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

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dual participant data

ClinicalTrials.gov number

Secondary identifying numbers

N0453162803

Study information

Scientific Title

The effects of patellar tape on neural correlates during knee joint proprioception tests using fMRI: a pilot study

Study objectives

The principle objective is to discover if there is any increase in brain activity when subjects perform a simple proprioceptive test with and without a piece of tape across the knee cap.

Ethics approval required

Old ethics approval format

Ethics approval(s) Added June 2008: approved by Salford and Trafford LREC, ref 05/Q1404/17.

Study design Pilot RCT

Primary study design Interventional

Secondary study design

Randomised controlled trial

Study setting(s) Not specified

Study type(s) Not Specified

Participant information sheet

Health condition(s) or problem(s) studied Musculoskeletal Diseases: Knee

Interventions

The subjects will lie in the scanner wearing shorts. A plastic block will support the thigh and knee at an angle of 45 degrees of knee inflexion. A strap will be placed over the hips to further limit head motion as a consequence of lower limb motion. Every effort will be made to control head movement by using a foam pad velcro strap and a bite bar. To ensure minimum ankle, foot and toe movements during the test, these joints will be placed in a neutral position and held by a temporary plaster cast and velcro straps. MR scanning using the BOLD technique will be performed using a 1.5 tesla machine. The scanning protocol will be based on a functional time series. Each time series will consist of 4 blocks of 4 conditions: knee joint extension to 0deg, extension to 20deg with or without patellar tape. Each condition will last 5 minutes consisting of 30 sec on (ie the task) and 30 sec off (no task) and will be triggered by an auditory command given by using headphones customised for fMRI experiments. A metronome will pace the movements using sound in order to impose a constant timing and equal no of cycles across conditions.

Patellar taping will then be applied. The order of tape/no tape will be randomised

The acquired images will be assessed carefully for head movement and in order to correct the confounding effects induced by head movement realignment parameters. To process the data, statistical parametric mapping will be used to display the significance of activation and to analyse functional and anatomical image. SPM is the most prevalent approach to characterising activity related changes (Friston et al 2000).

Intervention Type

Other

Phase Not Specified

Primary outcome measure

Neural processing in the brain as a result of application of patellar tape detected by the BOLD technique using fMRI.

Secondary outcome measures

No secondary outcome measures

Overall study start date 26/04/2005

Completion date

31/01/2007

Eligibility

Key inclusion criteria

8 healthy volunteers between the ages of 20-40 years will have refrained from any physical exercise for 3 days prior to the testing. They will sign a consent form after reading the study information sheet and after having had the opportunity to ask questions about any aspect of the study and their role.

There is no control group. All subjects will act as their own internal controls.

Participant type(s) Healthy volunteer

Age group Adult **Sex** Not Specified

Target number of participants 8 healthy volunteers

Total final enrolment

8

Key exclusion criteria

Added June 2008:

- 1. Histories of neurological or cardiovascular disease
- 2. Cochlear implants or any metal objects in the body
- 3. Cardiac or neural pacemakers
- 4. Histories of serious musculoskeletal injury in both lower limbs

Date of first enrolment 26/04/2005

Date of final enrolment 31/01/2007

Locations

Countries of recruitment England

United Kingdom

Study participating centre Clinical Specialist & Research Associate Manchester United Kingdom M13 9PT

Sponsor information

Organisation Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details The Department of Health, Richmond House, 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type Government

Website http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type Government

Funder Name

Central Manchester and Manchester Children's University Hospitals NHS Trust (UK)

Funder Name NHS R&D Support Funding

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

Study outputs

Output type Results article Details Date created 26/01/2012

Date added 09/08/2021

Peer reviewed? Yes

Patient-facing? No