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

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/08/2021	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Michael Callaghan

Contact details
Clinical Specialist & Research Associate
Centre for Rehabilitation Science
ARC Epidemiology Unit
School of Translational Medicine
University of Manchester
Oxford Road
Manchester
United Kingdom
M13 9PT
+44 0161 306 0542
michael.callaghan@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/01/2012	09/08/2021	Yes	No