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Centrally mediated pain after injury to the knee: A study of pain and function after knee fracture

Submission date
03/07/2024

Recruitment status
Recruiting

Registration date
11/07/2024

Overall study status
Ongoing

Last Edited
03/07/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Centrally mediated pain can affect people with knee arthritis. We are looking to see if it can occur in people who have a broken knee also. This will also let us know if there are other things that can affect pain after a broken knee such as mood or activity

Who can participate?
People aged 18 years or older, who have had a broken knee in the last 8 years can be involved in the study

What does the study involve?
The study will involve answering questionnaires and some tests of pain around your knee. These tests use a pressure-measuring device to measure pain threshold.

What are the possible benefits and risks of participating?
There are no direct benefits for participants but they will help us understand the disease more.

Where is the study run from?
This study is run by the Academic orthopaedic department at Nottingham University hospitals (UK)

When is the study starting and how long is it expected to run for?
February 2024 to July 2027

Who is funding the study?
NIHR Nottingham Biomedical Research Council (UK)

Who is the main contact?
Dr Chris Busby, christopher.busby@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
339920

Protocol serial number
24025

Study information

Scientific Title
Centrally mediated pain following injury to the knee: a Cross-sectional study of pain and function following intra-articular knee injury

Acronym
ExploreKNEE

Study objectives
To assess the prevalence of centrally mediated features in those who have suffered an intraarticular knee fracture. This will be achieved by evaluating if intra-articular knee injury has a link with centrally mediated pain and psychological distress. This may improve our knowledge about the relationship between knee injury, surgery, psychological distress and pain, which may help advance interventions to improve health outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Primary study design
Observational

Study design
Observational cross sectional study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Prevalence of centrally mediated pain after intraarticular knee trauma

Interventions
Participants will be located from a database of trauma and will complete initial questionnaires remotely with a proportion being purposively sampled. These sampled participants will be assessed with further questionnaires and quantitative sensory testing.

Intervention Type
Other

Primary outcome(s)
Measured at a single time point:
1. Features of centrally mediated pain measured using quantitative sensory testing (conditioned pain modulation, pressure algometry)
2. Central Aspects of Pain in the Knee Questionnaire (CAP-Knee)
3. Measures of Central sensitisation and neuropathic pain (Central sensitisation inventory (CSI), PainDETECT questionnaires)
4. Numerical Rating Scale (NRS)
5. Brief pain inventory (BPI)

Key secondary outcome(s)
Measured at a single time point:
1. Features of psychological distress measured using Hospital anxiety and depression scale (HADS)
2. Knee Function after trauma, measured using the The Knee Injury and Osteoarthritis Outcome Score (KOOS) and EQ-5D-5L

Completion date
01/07/2028

Eligibility

Key inclusion criteria
1. Adult participants who attended Nottingham University Hospitals under the care of orthopaedic trauma and underwent treatment for intraarticular knee injuries from 2015-2023.
2. Must include one or more of the injury groups outlined below and include an intraarticular component as defined in AO Classification (2018) (1):
2.1. Patella fracture
2.2. Tibial plateau fracture
2.3. Distal femur fracture
3. Able to give informed consent.
4. Able to complete required questionnaires.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Key exclusion criteria
1. Aged 17 years or under
2. Concomitant fracture involving another joint
3. Intra articular knee fracture that involves preceding prosthesis or implant.
4. Active malignancy
5. Pregnancy or breast feeding
6. People in custody of the police or incarcerated persons
7. Inability to read or write English.

Date of first enrolment
01/08/2024

Date of final enrolment
01/08/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR Nottingham Biomedical Research Centre

Alternative Name(s)
Nottingham Biomedical Research Centre, Nottingham Biomedical Research Centre - NIHR, NIHR Nottingham BRC, BRC, NIHR NBRC

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated will be available on request from Chris Busby - Christopher.busby@nhs.net

IPD sharing plan summary
Available on request