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Knee injury and the biological basis for outcomes: How does local and systemic inflammation affect outcomes including pain and function following knee injury, a prospective observational study

Submission date
05/06/2024

Recruitment status
Recruiting

Registration date
11/07/2024

Overall study status
Ongoing

Last Edited
18/06/2024

Condition category
Injury, Occupational Diseases, Poisoning

[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
This study aims to find out if there is a link between knee injury and pain that is mainly from the brain and spinal cord and not from the knee. The researchers will perform tests on the knee and use patient questionnaires to assess this. It is possible that the pain is linked to inflammation so blood samples and fluid from the knee will be taken to test this.

Who can participate?
Patients over 18 years old who have suffered a fracture that involves the knee joint

What does the study involve?
The study involves taking samples of blood and knee fluid up to three times after the injury, as well as two stool samples. Then as an outpatient patients will be reviewed every 3 months where they will undergo specialist knee pain tests and complete questionnaires on their pain and function.

What are the possible benefits and risks of participating?
There is a small risk of discomfort and infection from the sampling procedures. Occasionally aspiration of a swollen joint can have a pain-relieving effect.

Where is the study run from?
University of Nottingham (UK)

When is the study starting and how long is it expected to run for?
February 2023 to July 2028

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

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

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
340204

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 340204

Study information

Scientific Title
Knee injury: evaluation of biological Factors and Clinical Trials Study

Acronym
KneeFACTS

Study objectives
To evaluate if certain characteristics (such as injury severity and surgical insult), affect the inflammatory response in individuals with knee injury and if this has a relationship with psychology. This will improve our knowledge about the relationship between knee injury, surgery, psychological distress, pain and inflammation, which will help in advancing interventions to improve health outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Study design
Single-center single-cohort descriptive study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Development of centrally mediated pain in knee trauma

Interventions
Recruitment will be of patients with an intraarticular knee injury, both conservatively treated and operatively treated. The study involves taking samples of blood and synovial fluid up to three times after the injury, as well as two faecal samples. Then as an outpatient patients will be reviewed every 3 months where they will undergo specialist knee pain tests and complete questionnaires on their pain and function. The analysis of collected samples (blood and synovial fluid) will take place either within the University of Nottingham or transported to commercial providers for specialist analyses where a material transfer agreement has been arranged.

Intervention Type
Other

Primary outcome measure

Changes in cytokine levels and inflammatory marker levels in blood in response to injury at presentation, measured using ELISA at time of surgery (if occurring) at day 3 post-surgery (if still an inpatient), and day 7-8 post-surgery (if still an inpatient)

Secondary outcome measures
1. Changes in cytokine and inflammatory marker levels in knee synovial fluid measured using ELISA at presentation, at the time of surgery (if occurring) at day 3 post-surgery (if still an inpatient), and day 7-8 post-surgery (if still an inpatient)
2. Measured at 6 weeks, 3 months, 6 months, 9 months, 12 months post-injury/operation:
2.1. Changes in post-trauma pain phenotype over time measured with quantitative sensory testing, patient-reported outcome measures (PROMs) (numerical rating scale, central sensitisation inventory, PainDETECT)
2.2. The effect of knee injury on mental health measures measured with the Hospital Anxiety and Depression Scale
2.3. Knee function post-injury measured with PROMS (Knee Injury and Osteoarthritis Outcome Score [KOOS] and Central Aspects of Pain in the Knee [CAP-Knee])
2.4. Health-related quality of life score changes measured using EQ-5D-5L
3.0 Gut microbiome expression measured using faecal samples on discharge from hospital and at 6 months

Overall study start date
07/02/2023

Completion date
01/07/2028

Eligibility

Key inclusion criteria
1. Adult patients (>17 years old, no maximum age) who attend Nottingham University Hospitals under the care of orthopaedic trauma and are undergoing treatment for intraarticular knee injuries. Must include one or more of the injury groups outlined below and include an intraarticular component as defined in AO Classification (2018):
1.1. Patella fracture
1.2. Tibial plateau fracture
1.3. Distal femur fracture
2. Able to give informed consent
3. Able to complete required questionnaires

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
80

Key exclusion criteria
1. Aged 17 years or under
2. Concomitant fracture involving another joint
3. Taking anticoagulants (direct oral anticoagulants [DOACs], warfarin) or coagulopathy
4. Intra articular knee fracture that involves preceding prosthesis or implant.
5. Significant soft tissue injury making aspiration not feasible or safe as determined by one of the investigative team
6. Presence of local (knee) or systemic infection
7. Immunomodulating medication or treatments with systemic impact
8. Systemic chronic inflammatory diseases
9. Active malignancy
10. Pregnancy or breastfeeding
11. People in the custody of the police or incarcerated persons
12. Inability to read or write English.
13. People with significant mental health disease under section

Date of first enrolment
01/08/2024

Date of final enrolment
01/08/2027

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen's Medical Centre
Derby Road
Nottingham
United Kingdom
NG81FS

Sponsor information

Organisation
University of Nottingham

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Sponsor type
University/education

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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

Publication and dissemination plan
The results will be published in peer-reviewed journals and form part of a PhD thesis

Intention to publish date

01/08/2028

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository: University of Nottingham servers

IPD sharing plan summary

Stored in non-publicly available repository