

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	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/07/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/06/2024	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact name

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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)

notYetSubmitted

Study design

Single-center single-cohort descriptive study

Primary study design

Observational

Study type(s)

Other

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(s)

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)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Queen's Medical Centre

Derby Road

Nottingham

United Kingdom

NG81FS

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 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