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Understanding the disease process of young patients with a meniscal tear of the knee and response to treatment

Submission date
22/02/2021

Recruitment status
No longer recruiting

Registration date
08/04/2021

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The meniscus is a cartilage based structure within the knee which is susceptible to damage or tears following high energy injury or low energy injury in a knee with signs of arthritis. Treatment for meniscal tears can include either physiotherapy or surgery where the damaged meniscus is removed. Recent high quality studies have shown physiotherapy is as effective as surgery in patients over 55. A potential reason for this is in patients over 55 there may be coexisting arthritis within the knee which is the source of symptoms rather than the meniscal tear. There is a clear need for high quality trial in younger patients aged under 55. Before a trial is commenced it is imperative to understand the trial population better.
The purpose of this study is to identify the symptoms patient present with, the presence of signs of arthritis on imaging and whether these features influence treatment outcome. We also aim to explore patient experiences of living with a meniscal tear.

Who can participate?
Patients under 55 years old, with an isolated meniscal tear.

What does the study involve?
We will follow up patients to identify the symptoms and imaging findings patients present with. We will then follow up these patients over one year to identify if these symptoms or imaging signs affect treatment success. In addition we will identify the current treatment pathways for patients with a meniscal tear.
20 participants from the main study will be invited to take part in interviews where we aim to identify patient experiences on living with a meniscal tear and views on a future large scale trial.

What are the possible benefits and risks of participating?
No direct risks or benefits.
This study will provide clinicians with a greater understanding of meniscal tears in young patients and help aid treatment decisions.

Where is the study run from?
University Hospital Coventry and Warwickshire (UK)

When is the study starting and how long is it expected to run for?
December 2018 to May 2022.

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Imran Ahmed, Imran.ahmed4@nhs.net

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
259098

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 41432, IRAS 259098

Study information

Scientific Title
The MEniscal TeaR Outcome (METRO) study

Acronym

METRO

Study objectives
The aim is to investigate factors that explain the variability in patient reported outcome measures following treatment for meniscal tears.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/04/2019, Black Country REC board (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8284; blackcountry.rec@hra.nhs.uk), ref: 19/WM/0079

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Presentation, treatment, and recovery for a meniscal tear of the knee

Interventions
Potential participants will be identified by attending clinical teams or clinical research teams by screening orthopaedic clinic lists e.g. fracture clinic, acute knee clinic or an elective knee clinic. Potential participants will be approached for the study once they have had their clinical consultation. There will be no change to their standard clinical care determined by the health care professional who reviews the patient in the clinic. If they meet the study criteria they will be provided with a patient information sheet and consent form. The potential participant will then have time to review the study information and can either provide written confirmation of consent during that clinic visit or at a later date. If the participant would like more time to review the information, a member of the study team will take contact details of the participant (with documented verbal consent) and will contact the participant at a later date to address any queries.
The participant can then provide written confirmation of consent via post.
Once confirmation of consent has been received, participants will complete a baseline questionnaire. This will collect baseline demographics including age, gender and body mass index. The questionnaire will also collect information regarding the knee injury including the possible date and mechanism of injury as well as key symptoms. Three baseline patient-reported

outcome tools will be collected at this point: Western Ontario Meniscal Tear Evaluation Tool (WOMET), Knee Injury and Osteoarthritis Outcome Score (KOOS4) and EuroQol (EQ-5D-5L). The study team will also review the Magnetic Resonance Imaging (MRI) scan used to confirm the diagnosis of a meniscal tear as part of standard clinical practice. This scan will be reviewed for type/pattern and location of the tear, assessment of arthritis using Whole Organ Magnetic resonance Score (WORMS), anonymised scans will also be reviewed by IMorphics ltd to assess bone volume (a novel measure of arthritis).
Participants will receive a 3-month questionnaire where they will complete the WOMET, Eq-5D-5l and Patient Global Impression of change score (PGIC). In addition, the 3-month questionnaire will also collect adverse events. This questionnaire can either be completed face to face, via post or email depending on participant preference. Participants will then receive a 6-month questionnaire including WOMET, EQ-5D-5L, PGIC and adverse events. This can again be completed as above.
Final data collection will occur 12 months following recruitment to the study where we will collect WOMET, EQ-5D-5L, PGIC, KOOS4 and adverse events.
If a participant expresses interest on the initial consent form a small number of participants (20) will be invited to take part in semi structured interviews (METRO Interview study). This can either be done over the phone or face to face depending on participant preference. Interviews will last 45-60 minutes and will explore participant experience of living with a meniscal tear and their views on a future trial. All interviews will be audio recorded in order to be transcribed at a later date. Quotations may be used from the interviews in future medical publications but all patient identifiable information will be removed. Interviews will take place 3-9 months following recruitment.
The study will end after the 12-month follow-up questionnaire has been received.

Intervention Type
Other

Primary outcome measure
Meniscal tear disease-specific quality of life measured using the Western Ontario Meniscal Evaluation Tool (WOMET) at baseline, 3, 6 and 12 months

Secondary outcome measures
1. Knee injury impact on person measured using the Knee injury and Osteoarthritis outcome score 4 (KOOS) at baseline and 12 months
2. Quality of life measured using the EQ-5D-5L at baseline, 3, 6 and 12 months
3. Participant perception of improvement measured using the Patient global assessment of change (PGIC) at 3, 6 and 12 months
4. Surgery for the meniscal tear (yes/no) measured by self-report at 3, 6 and 12 months

Overall study start date
01/12/2018

Completion date
30/05/2022

Eligibility

Key inclusion criteria

1. Provision of written informed consent
2. Age 18 – 55 years
3. Presence of a MRI confirmed meniscal tear

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200

Key exclusion criteria
1. Anterior cruciate ligament or other major knee ligament injury. This does not include a previous unrelated healed medial collateral ligament tear or a meniscal root tear (which is considered a type of meniscal tear in this study)
2. Associated intra-articular fracture of the tibial plateau or femur. Previous fractures not thought to be related to the tear are not an exclusion criteria for the study
3. Previous knee surgery
4. Previous entry into the present study (i.e other knee)
5. Unable to provide informed consent or undertake study procedures

Date of first enrolment
01/06/2019

Date of final enrolment
30/07/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Coventry and Warwickshire
Clifford Bridge Road
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Study participating centre
Royal Orthopaedic Hospital
The Woodlands
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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30 Brookfield Rd
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B30 3QY

Study participating centre
St. Mary's Hosptial
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Study participating centre
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Sponsor type
University/education

Website
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ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: DRF-2018-11-ST2-030

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/05/2023

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		12/07/2020	05/03/2021	Yes	No
Participant information sheet	version v3		09/04/2021	No	Yes
HRA research summary			26/07/2023	No	No

Other publications	Qualitative thematic analysis of semistructured interviews to identify key patient experiences	14/01/2025	21/01/2025	Yes	No