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Comparison of two different approaches to knee replacement surgery

Submission date
15/01/2020

Recruitment status
No longer recruiting

Registration date
16/03/2020

Overall study status
Completed

Last Edited
26/04/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Total knee replacements are currently done through a straight or curved incision over the front of the knee. There are a few studies that have looked at wound stresses in cadavers and at oxygen tension in the different wounds. But there has not been a randomised controlled trial to test which incision type is best for wound ooze. The aim of this study is to compare the two types of incision.

Who can participate?
Adult patients, aged 18 years or older, undergoing planned primary Total Knee Replacement surgery in Weston General Hospital.

What does the study involve?
Patients who take part in this study will have a knee replacement using either a straight or a curved incision (the skin cut through which the operation is done). The actual operation will otherwise be exactly the same for both groups of people. After the operation we will measure how well the wound is healing up by checking how much the dressings get marked by fluid oozing out of the wound each day. Both of the types of incision are commonly used for knee replacements so we are not 'trying out' anything new and everyone who takes part will have a currently approved treatment. When patients come to their routine 6 week post-op review appointment they will be asked what they think of the surgical scar by completing a questionnaire.

What are the possible benefits and risks of participating?
As the study is comparing two already commonly used ways of making the incision for a knee replacement there are, in theory, no additional risks over and above the routine risks of having a knee replacement. Taking part in the trial will not add any significant risk to the process of having a knee replacement.

Where is the study run from?
Weston General Hospital, UK

When is the study starting and how long is it expected to run for?
February 2020 to February 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Mr John Mullan
john.mullan@nhs.net

Contact information

Type(s)
Scientific

Contact name
Mr John Mullan

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
539

Study information

Scientific Title
Knee Incision Trial: a randomised controlled trial to compare wound ooze after midline vs curved medial para-patellar skin incisions in knee replacement

Acronym
KIT

Study objectives

There is a difference in wound ooze after a knee replacement when a medially curved skin incision around the knee-cap (curved towards the inside of the leg) is used as compared to a straight incision in the midline.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/12/2019, Yorkshire & The Humber - Sheffield Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8208; nrescommittee.yorkandhumber-sheffield@nhs.net), ref: 19/YH/0316

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Conditions requiring knee replacement

Interventions
All patients recruited to the study will have a routine Total Knee Replacement as they would normally on the NHS in Weston General Hospital. On admission they will be randomised into one of the two study arms. This randomisation will be done by use of a random number generator and the outcome in a sealed envelope to be opened on the day of surgery. At this point the patient will enter either the curved incision or the straight incision arm of the trial. In the curved incision arm the patient will receive a curved medial para-patellar incision for the knee replacement, and in the straight incision arm they will receive a straight midline incision. With the exception of the shape of the incision the rest of the operation will proceed as normal NHS care for a knee replacement. Postoperatively the wound healing will be assessed by measuring the wound ooze. This is assessed by measuring the amount of marking on the dressings each day using a validated method. The patient's satisfaction with the wound will be measured using a validated wound assessment tool at the 6 week post-op review. This will be the extent of the follow-up for the purpose of the study but this will be the usual follow-up that the patient would receive normally, were they not in the study.

Intervention Type

Procedure/Surgery

Primary outcome measure
Wound ooze on day 1 to day 4, using graph paper printed onto acetate sheets which can by laid onto the dressing, allowing the size of dressing marking to be measured by counting the number of squares on the graph paper which are involved

Secondary outcome measures
1. The length of inpatient stay (days) following the surgery
2. Whether or not an expensive 'PICO' dressing is required (only if the patient has persistent wound ooze more than 2x2cm at day 4)
3. Patient satisfaction with the appearance and function of the scar as assessed by means of a validated wound scoring system, the Patient and Observer Scar Assessment Scale (POSAS) (the patient assessment part of this questionnaire) at week 4 and week 6 post-operatively

Overall study start date
01/08/2018

Completion date
01/02/2024

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Undergoing planned primary Total Knee Replacement surgery in Weston General Hospital

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Patients for revision procedures
2. Previous open procedures on the knee
3. Bleeding disorders or medical conditions/complications requiring therapeutic anticoagulation (eg DVT, PE, MI), even if these complications occur post-operatively
4. History of previous trauma to the knee
5. Known allergy to skin adhesives
6. Deviation from post-operative protocol

7. Significant medical condition which has an effect on wound healing (eg diabetes or rheumatological disease)
8. Obesity

Date of first enrolment
02/03/2020

Date of final enrolment
01/03/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Weston General Hospital
Grange Road
Weston-Super-Mare
United Kingdom
BS23 4TQ

Sponsor information

Organisation
Weston Area Health NHS Trust

Sponsor details
Grange Road
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Sponsor type
Hospital/treatment centre

Website
http://www.waht.nhs.uk/

ROR

https://ror.org/03fpf5m04

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
We intent to present the results in national / international meetings. Also, we intend to publish in a peer reviewed journal.

Intention to publish date
01/08/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (John Mullan) at kneetrial@outlook.com. The data will become available on completion of the study, this will be the anonymised raw data as well as details of the statistical analysis (although the analysis will be published with the results). The data will be held for 5 years in accordance with the trust R&D Department policy, participants will be assigned a trial number on entering the study and their personal details will be held in a secure server for the duration of the study and deleted on completion of the study. Stastical analysis will be performed by the statistician in the Trust. Data will be collected and summarised with descriptive statistics. Comparison between groups will be made using Students t test for parametric data or the Mann-Whitney U test for non-parametric data. Statistical significance will be with a two-tailed alpha of 0.05, and all statistical testing will be conducted using IBM SPSS v. 24.0.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No