ISRCTN06592799 https://doi.org/10.1186/ISRCTN06592799

Study to determine the influence of incision position on physiological and biochemical changes in tissue skin flaps after surgery for total knee replacement.

Submission date
16/09/2014

Recruitment status
No longer recruiting

Registration date
07/10/2014

Overall study status
Completed

Last Edited
18/05/2017

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
During knee replacement surgery an incision (or cut) has to made in the skin covering the knee so that the surgeon can to access the knee joint. This causes some disruption to the blood supply to the skin which can cause complications such as delayed wound healing. The nerves to the skin can also be damaged, resulting in loss of sensation or numbness in this area. The cut itself can be made in a number of different places around the knee and the choice taken is often down to the personal preference of the surgeon performing the operation. Here, we want to look at the blood flow and nerve sensation to the skin over the knee so that surgeons can decide where best to make the cut for knee replacement surgery.

Who can participate?
Adults aged 18 or over who need a total knee replacement

What does the study involve?
Three extra examinations are carried out on the patients knees. The first is testing nerve sensation in the skin. This is done using cotton wool to test for light sensation and a blunt pin to test for pinprick sensation. It is carried out both before and after surgery. The second test involves using an ultrasound machine to measure the blood flow to the skin. Ultrasound is completely safe and pain free. This is done before surgery, 1 day after surgery and before the patient leaves hospital. The third procedure involves inserting a small thin tube, called a microdialysis catheter, under the skin of the knee. This is done during the operation and is left in place for 24 hours afterwards. The tube is plastic, flexible and about the thickness of a needle from a syringe. The tube collects small samples of fluid from underneath the skin which are then analysed. The data allows us to determine if the position of the surgical cut makes any difference to the cells in the skin around where the cut is made.

What are the possible benefits and risks of participating?
There are no direct benefits to participating. There is a potentially higher risk of wound infection.

Where is the study run from?
Glasgow Royal Infirmary (UK).

When is the study starting and how long is it expected to run for?
May 2011 to May 2013.

Who is funding the study?
Glasgow Orthopaedic Research Charitable Trust (UK).

Who is the main contact?
Mr Mark Blyth
mark.blyth@ggc.scot.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Mr Mark Blyth

Contact details
Orthopaedic Research Unit
Glasgow Royal Infirmary
Gatehouse Building
84 Castle Street
Glasgow, G4 0SF
0141 232 0805
Glasgow
United Kingdom
G4 0SF
-
mark.blyth@ggc.scot.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.2

Study information

Scientific Title
Study to determine the influence of incision position on physiological and biochemical changes in tissue skin flaps after surgery for total knee replacement: a randomised controlled trial

Study objectives
We hypothesis that the position of the surgical incision used for total knee replacement surgery influences the local bloodflow and biochemical response of the surrounding cells.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Committee, 12/3/2010, ref. 10/S0704/8

Study design
Randomised 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
Osteoarthritis

Interventions
Patients are allocated to treatment via an online randomisation system provided by www.sealedenvelopes.com. Patients either received a midline incision or medial parapatellar incision. All other aspects of the knee replacements surgery including the implants and instruments used was standardised.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. To determine the influence of incision position for total knee replacement on cutaneous blood flow
This measure at baseline (pre-operatively) and then at 24 hours (Day 1) and 72 hours (Day 3) post-operatively. Blood flow was measured using Laser Speckle Contrast Blood Perfusion Imager, Moor FLPI (Moor Instruments, Axminster, UK).

Secondary outcome measures
1. To determine the influence of incision position for total knee replacement on metabolic accumulations in the interstitial fluid of the resultant skin flap
2. To determine the effects of incision position on nerve innervation of the overlying skin flap during total knee replacement and patient perception of post operative pain
3. To determine rates of early sites specific infection for both midline and medial parapatellar incisions

Overall study start date
10/05/2011

Completion date
10/05/2013

Eligibility

Key inclusion criteria
1. Patients who require total knee replacement
2. Sex - Male or Female subjects
3. Age Minimum age of 18, no upper age limit
4. Subjects, who in the opinion of the Investigator are able to understand this investigation, co operate with the investigation procedures
5. Subjects who are able to give voluntary, written informed consent to participate in this investigation and from whom consent has been obtained

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Patients who require revision knee surgery
2. Patients who have had previous surgery or trauma to the knee that may influence the blood supply to the skin covering the knee
3. Patients who are clinically obese
4. Patients who have vascular disease
5. Subjects who are currently involved in any injury litigation claims

Date of first enrolment

10/05/2011

Date of final enrolment
10/05/2013

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Orthopaedic Research Unit
Glasgow
United Kingdom
G4 0SF

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

Sponsor details
NHS GGC R&D Dept,
Western Infirmary/gartnavel General, Dumbarton Road, Glasgow, G11 6NT
Glasgow
Scotland
United Kingdom
G11 6NT

Sponsor type
University/education

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Glasgow Orthopaedic Research Charitable Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/04/2015		Yes	No