

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 07/10/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 18/05/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

During knee replacement surgery an incision (or cut) has to be made in the skin covering the knee so that the surgeon can 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
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Contact information

Type(s)
Scientific

Contact name
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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 hypothesise 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