

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

<b>Submission date</b> 16/09/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 07/10/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/05/2017	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Osteoarthritis

### **Interventions**

Patients are allocated to treatment via an online randomisation system provided by [www.sealedenvelopes.com](http://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(s)**

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).

### **Key secondary outcome(s)**

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

### **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, cooperate 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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

Scotland

**Study participating centre**

**Orthopaedic Research Unit**

Glasgow

United Kingdom

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## Sponsor information

### Organisation

NHS Greater Glasgow and Clyde (UK)

### ROR

<https://ror.org/05kdz4d87>

## Funder(s)

### Funder type

Charity

### Funder Name

Glasgow Orthopaedic Research Charitable Trust (UK)

## Results and Publications

### 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?
<a href="#">Results article</a>	results	16/04/2015		Yes	No