

# A trial comparing skin preparation regimens in primary knee arthroscopy

<b>Submission date</b> 19/10/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/10/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/05/2017	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Knee arthroscopy is a type of keyhole surgery where a telescope (arthroscope) is used to investigate and diagnose knee problems such as inflammation or injury. An antibacterial skin cleaner is used to prepare the skin before the operation. The aim of this study is to see if there is any difference in effectiveness between two antibacterial skin cleaners (chlorhexidine or betadine) and the number of times they are used.

### Who can participate?

Patients aged over 18 undergoing knee arthroscopy.

### What does the study involve?

Participants will be randomly allocated to be treated with either chlorhexidine single preparation, chlorhexidine double preparation, betadine single preparation or betadine double preparation. The first skin preparation is applied by a trained nurse on the ward who will then cover the knee in a sterile dressing. The second preparation is applied by the surgeon when the patient is asleep just before arthroscopy. When the skin preparation is dry, a small skin swab (cotton wool bud) will be taken from the area where the arthroscope is entering. This is sent to the laboratory for tests.

### What are the possible benefits and risks of participating in the study?

There will be no difference with treatment for the patients. The study does not interfere with their arthroscopy and has been discussed with their surgeon. There are no immediate gains from entering the trial for each patient and their care will not be affected. There are no specific new side effects from the study as the skin preparations (chlorhexidine and betadine) are already used daily.

### Where is the study run from?

The study will take place at Arrowse Park Hospital and Clatterbridge Hospital (UK).

### When is the study starting and how long is it expected to run for?

The study ran from December 2011 to December 2012.

Who is funding the study?

The study is being funded by Wirral University Hospital NHS Trust (UK).

Who is the main contact?

Mr Glyn Thomas

Tel: +44 (0)1516785111

## Contact information

### Type(s)

Scientific

### Contact name

Mr Glyn Thomas

### Contact details

Wirral University Teaching Hospital

Arrowe Park Road

Upton

Wirral

United Kingdom

CH49 5PE

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

11/NW/0222

## Study information

### Scientific Title

A randomised trial comparing the efficacy of skin preparation regimens in native knee arthroscopy

### Study objectives

We hypothesise that there is no clinical or microbiological difference in a double or single preparation with either chlorhexidine or betadine when concerning primary knee arthroscopy

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

NRES committee North West - Liverpool Central, 23/08/2011, ref: 11/NW/0222

**Study design**

Randomised trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Screening

**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**

Orthopaedics/knee arthroscopy

**Interventions**

Either chlorhexidine or betadine preparation (single or double preparation):

1. Chlorhexidine single preparation
2. Chlorhexidine double preparation
3. Betadine single preparation
4. Betadine double preparation

**Intervention Type**

Procedure/Surgery

**Phase**

Not Applicable

**Primary outcome measure**

Microbiological evidence of growth

**Secondary outcome measures**

Clinical evidence of infection

**Overall study start date**

01/12/2011

**Completion date**

01/12/2012

**Eligibility****Key inclusion criteria**

1. Age over 18 years
2. Patients competent to consent for themselves
3. Patients undergoing primary arthroscopy as a routine out patient

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

200 patients

**Key exclusion criteria**

1. Previous joint arthroplasty on affected limb
2. Known infected native joint
3. Concurrent infection or long term antibiotic prescription for infection

**Date of first enrolment**

01/12/2011

**Date of final enrolment**

01/12/2012

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Wirral University Teaching Hospital**

Wirral

United Kingdom

CH49 5PE

**Sponsor information**

**Organisation**

Wirral University Teaching Hospital (UK)

**Sponsor details**

c/o Professor Roderick Owen  
Research and development dept  
Arrowe Park Road  
Upton  
Wirral  
England  
United Kingdom  
CH49 5PE

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/05cv4zg26>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Wirral University Teaching Hospital (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