

A trial comparing skin preparation regimens in primary knee arthroscopy

Submission date 19/10/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 09/10/2014	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 19/05/2017	Condition category Surgery	☐ Individual participant data ☐ 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

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised trial

Study type(s)

Screening

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(s)

Microbiological evidence of growth

Key secondary outcome(s)

Clinical evidence of infection

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

United Kingdom

England

Study participating centre

Wirral University Teaching Hospital

Wirral

United Kingdom

CH49 5PE

Sponsor information**Organisation**

Wirral University Teaching Hospital (UK)

ROR

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

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Wirral University Teaching Hospital (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration