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A trial comparing skin preparation regimens in primary knee arthroscopy

Submission date
19/10/2011

Recruitment status
No longer recruiting

Registration date
09/10/2014

Overall study status
Completed

Last Edited
19/05/2017

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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 Arrowe 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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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
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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