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Post-operative wound management

Submission date 05/09/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/09/2012	**Overall study status** Completed	
Last Edited 16/04/2018	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12054

Study information

Scientific Title

Evaluation of a postoperative wound management protocol using negative pressure wound therapy in primary arthroplasty patients

Study objectives
Most postoperative protocols for patients undergoing primary total hip and knee replacements (arthroplasty) require the patient to have a dry wound before being discharged from hospital. This has recently become more important following the introduction of strict guidelines surrounding the use of heparin (a bloodthinning treatment) to reduce the risk/occurence of postoperative blood clots. Oozing from wound sites following such surgery continues to be a common complication in a large number of patients with a resulting delay in hospital discharge and inconvenience to the patient. This increase in stay incurs extra costs on the various trusts and the NHS. The use of Negative Pressure Wound Therapy (NPWT) is a relative recent idea which has shown very promising results in trauma surgery and other fields of surgery. However, there is very limited literature relating to its efficacy and costeffectiveness in arthroplasty surgery. Arthroplasty patients appear to be the ideal candidate for NPWT. Using the standard method of dressings, patients may require multiple changes of dressing and therefore early exposure of the wound. However, due to the mild to moderate nature of wound oozing in arthroplasty patients, is it thought that a single application of PICO dressing is sufficient for the whole period of wound healing.

More details can be found at http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=12054

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 18 May 2012, ref: 12/SW/0094

Study design
Randomised interventional 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
Musculoskeletal surgery

Interventions

Control group
The control group will receive the standard dressings post-operatively

Study group
The study group will receive PICO negative pressure wound therapy post-operatively for 7 days

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
To introduce a new post-operative wound management protocol based on using PICO NPWT.

Secondary outcome measures
No secondary outcome measures

Overall study start date
16/08/2012

Completion date
16/08/2013

Eligibility

Key inclusion criteria
1. Patients undergoing primary total hip or knee replacement
2. Patients with no contraindications for PICO NPWT or standard postoperative dressings
3. Patients who are over 18 years of age and have given informed consent to participant
4. Male and female participants

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 220

Key exclusion criteria
1. Patients undergoing revision arthroplasty surgery
2. Patients with a known history of poor compliance with medical treatment

3. Patients with known allergies to either product components (silicone adhesives and polyurethane films (direct
contact with incision), acrylic adhesives (direct contact with skin), polyethylene fabrics and superabsorbent powders (polyacrylates)
4. Patients on warfarin therapy (these patients may have an increased exudate and also a prolonged stay in hospital following surgery whilst trying to achieve therapeutic INR (international normalized ratio) levels an indication of how well the patient's blood clots
5. Patients who do not give informed consent to participate in this study

Date of first enrolment
16/08/2012

Date of final enrolment
16/08/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Robert Jones & Agnes Hunt Orthopaedic & District Hospital
Oswestry
United Kingdom
SY10 7AG

Sponsor information

Organisation
Robert Jones & Agnes Hunt Orthopaedic & District Hospital

Sponsor details
Twmpath Lane
Oswestry
England
United Kingdom
SY10 7AG

Sponsor type
Hospital/treatment centre

Website
http://www.rjah.nhs.uk/

ROR
https://ror.org/030mbcp39

Funder(s)

Funder type
Industry

Funder Name
Smith & Nephew Medical Ltd

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	01/08/2016		Yes	No