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Post-operative wound management

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
To introduce a new post-operative wound management protocol based on using PICO NPWT.

Key secondary outcome(s))
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Robert Jones & Agnes Hunt Orthopaedic & District Hospital

ROR
https://ror.org/030mbcp39

Funder(s)

Funder type
Industry

Funder Name
Smith & Nephew Medical Ltd

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?
Results article	results	01/08/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes