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The Bluebelle pilot trial: Is it possible to recruit participants to a trial of different methods of dressing surgical wounds, one of which is to use no dressing?

Submission date
18/09/2015

Recruitment status
No longer recruiting

Registration date
20/10/2015

Overall study status
Completed

Last Edited
07/11/2023

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Wound infections are a common complication after surgery, which are a major cost for the NHS. The skin usually acts as a barrier against infection, protecting the blood and internal organs. When a cut is made during an operation to allow the surgery to be performed (surgical site), bacteria can potentially enter the body causing an infection. Wound dressings are commonly used to prevent infections of surgical sites in adults, however this practice is controversial. There is not enough evidence to say that wound dressings can help prevent surgical site infections (SSI). For example, in children it is rare to use wound dressings after surgery and the rate of SSI's does not seem to have been affected by this. Previously, healthcare professionals and patients were interviewed, in order to find out their opinions about different types of dressings. The aim of this initial study is to look at the use of different would dressings in order to reduce the amount of SSI's. This study will also show whether it would be feasible to carry out a larger study looking at the use of different dressings on surgical wounds.

Who can participate?
Adult surgery patients who be having subcuticular sutures for wound closure.

What does the study involve?
Participants are randomly allocated into one of three groups. After undergoing their scheduled surgical procedure, the surgical site is sewn up with stiches (sutured) and then treated in different ways. For those in the first group receive a "simple dressing". This involves a covering that it directly placed over the whole of a closed-up wound. Those in the second group receive a "tissue adhesive-as-a-dressing". This is "glue" that is applied directly to the skin to "seal" the wound edges together. Those in the third group do not receive any covering of their wound after their operation. Thirty days later, all participants visit the clinic for a follow up examination of their wound.

What are the possible benefits and risks of participating?
This study does not have any specific benefits for participants, however it will help increase knowledge which could help future patients. There are no risks of participating in this study, as all three techniques are currently used by surgeons. If a wound problem occurs (e.g. infection or leakage) it will be treated in the normal way.

Where is the study run from?
1. Bristol Royal Infirmary (UK)
2. Southmead Hospital Bristol (UK)
3. Queen Elizabeth Hospital Birmingham (UK)

When is the study starting and how long is it expected to run for?
November 2015 to August 2016

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Ms Helen Talbot

Contact information

Type(s)
Public

Contact name
Prof Jane Blazeby

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SU/2014/4748

Study information

Scientific Title
The Bluebelle Study: a feasibility study of three wound dressing strategies in elective and unplanned surgery – Phase B

Study objectives
This pilot randomised controlled study is to establish whether it is possible to carry out a major randomised study to compare the effectiveness and cost-effectiveness of simple dressing, tissue adhesive-as-a-dressing and no dressing to: reduce surgical site infection (SSI) and improve aspects of wound management and patients' experience of the care of their surgical wounds following elective and unplanned abdominal and obstetric (caesarean section) surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Health Research Authority - NRES Committee South West - Frenchay. 24/02/2015, ref: 15 /SW/0008

Study design
Multi-centre pilot randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgical site infections

Interventions
Participants, confirmed as having provided consent and as eligible for the study, will be randomised via a secure web-based database. Participants will be randomised to one of six groups, comprising all permutations of three wound dressing strategies (see below) and two times of disclosure of allocation to a dressing strategy (before or after wound closure).

1. Simple Dressing: A covering (opaque or transparent) that is directly applied to an already closed wound, over the entirety of the wound. It has adherent properties around its perimeter, or, its entire surface which is in contact with the skin. It may or may not have absorbent properties.

2. Tissue adhesive-as-a-dressing: Tissue adhesives are topical skin adhesives and in this study they will be applied to the surface of an already closed primary wound, acting as a dressing. They will not be applied with the intention to close the wound (i.e. below skin level), and will be applied according to the manufacturers' instructions for use after wound closure.

3. 'No' dressing: For those allocated to no dressing, at the end of the operation when the skin has been closed, no dressing at all or tissue adhesive is applied to the wound. The wound is therefore left exposed without a covering as is the standard approach for many types of surgery.

For all of the interventions, a simple gauze swab can be applied to an area that is, for example, oozing. This may be taped in place temporarily (but not around its entire perimeter) and will not have therapeutic properties. If the oozing continues the clinical team may apply any dressing of choice to the wound(s) (or re-suture it if necessary). This will be documented in the CRFs.
Wounds will be treated pragmatically and dressings left on as per normal practice.
The follow-up duration is 4-8 weeks from wound closure, (the same for the 3 arms) and includes:
Completion of: a questionnaire measure relating to the participant's management of the wound by a health care professional within 24 hours prior to discharge) and a questionnaire relating to the experience of the wound(s) by the participant within 48 hours of discharge. (Day Cases: Completion of Wound Experience and Practical Wound Management questionnaires within 48 hours of discharge).
On about day 15 and, where possible, at any time the participant considers there is a problem with their wound: Completion of an EQ-5D-5L (electronically or paper version if no access to electronic version).
For the 4-8 week follow-up assessment (which can be by phone or at clinic visit/home visit for women who have had a C-section):
Completion of a participant reported measure of SSI prior to a clinician assessment and a health status questionnaire (EQ-5D 5L) and provide information on any adverse events and use of health services since discharge from hospital. The clinician will complete a standard reference assessment and then the SSI measure.
Wound photos may be taken, with appropriate consent and in adherence to local policy, by clinicians (in theatres and/or at 30 day follow-up) and/or participants (for 30 day assessment and at any time they consider there to be a problem with their wound(s). Photos will be submitted to a secure database and will facilitate the exploration of a method for remote and blinded assessment of wounds using digital photography.

Intervention Type
Procedure/Surgery

Primary outcome measure
To establish whether recruitment into the main trial is possible, by recording the number of patients screened, eligible and randomised into the pilot trial.

Secondary outcome measures
1. Health status is measured using the EQ-5D-5L will be collected at baseline, day 15, 4-8 weeks and between these time points if a participant considers that there is a problem with the wound (s)
2. Participant symptom experience is measured using the Wound Experience Questionnaire will be completed within 48 hours of discharge
3. Practical wound management is measured using the Wound Management Questionnaire will be completed by a nurse up to 24 hours before discharge if the participant is an inpatient or up to 48 hours after discharge if the participant is a day case

4. Surgical site infection post discharge is measured using the Wound Healing (SSI) questionnaire will be completed by the participant and a member of the research team at the 4-8 week assessment. A member of the research team will also complete a reference SSI assessment at the 4-8 week assessment.
5. Qualitative research will be carried out alongside the trial to investigate facilitators and barriers to recruitment and possible reasons for non-adherence

Overall study start date
01/11/2015

Completion date
16/12/2016

Eligibility

Key inclusion criteria
1. Adult patients aged 16 years or over
2. Patients undergoing primary elective or unplanned abdominal general surgery (including, but not limited to gastrectomy for benign or malignant disease, cholecystectomy, anti-reflux procedures, hepatic resection, small or large bowel resection for benign or malignant conditions, abdominal wall hernia surgery (inguinal, femoral, incisional, epigastric and paraumbilical)) or elective or unplanned obstetric surgery (caesarean section). (NB Potential participants undergoing simultaneous abdominal and chest surgery are eligible but only the abdominal wounds will be included in the study interventions)
3. The wound is intended to be closed at the end of the procedure with sutures or clips
4. The potential participant is willing to attend follow-up for 4-8 weeks

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
330

Total final enrolment
394

Key exclusion criteria
1. Patients who have undergone abdominal or other major surgery less than three months before the index operation
2. Patients who have allergies to dressings or other contraindication to dressings
3. Patients undergoing groin surgery

4. Patients undergoing surgery which result in only internal wounds (e.g. intra vaginal surgery)
5. Prisoners and adults lacking capacity to consent
6. Ability to read/understand English

Date of first enrolment
01/12/2015

Date of final enrolment
31/08/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Royal Infirmary
University Hospitals Bristol NHS Foundation Trust
Queens Building
Upper Maudlin Street
Bristol
United Kingdom
BS2 8HW

Study participating centre
Southmead Hospital Bristol
North Bristol NHS Trust
Southmead Road
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Queen Elizabeth Hospital Birmingham
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Medical Centre
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust

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Bristol Royal Infirmary
Upper Maudlin Street
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United Kingdom
BS2 8HW
+44 117 3420233
research@UHBristol.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A final report will be submitted for publication in the NIHR Journals Library in 2017, as required by the contract for funding for the trial. We also intend to publish aspects of the study, primarily relating to its feasibility, in peer reviewed journals.

Intention to publish date
01/01/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		26/11/2017		Yes	No
Other publications		24/05/2016	25/01/2019	Yes	No
Other publications		01/11/2016	25/01/2019	Yes	No
Other publications		01/07/2017	25/01/2019	Yes	No
Other publications		22/09/2016	25/01/2019	Yes	No
Results article	results	01/02/2019	25/01/2019	Yes	No
Results article	results	01/08/2019	09/08/2019	Yes	No
HRA research summary			28/06/2023	No	No
Protocol article		29/08/2017	07/11/2023	Yes	No