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The Bluebelle Study: complex, simple and absent wound dressings in elective surgery: Phase A

Submission date
18/03/2014

Recruitment status
No longer recruiting

Registration date
20/03/2014

Overall study status
Completed

Last Edited
09/08/2019

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Wound infections are a common complication of surgical procedures, and are a major cost for the NHS as well as a cause of pain, discomfort and inconvenience for patients. Although every effort is made to reduce the risk of wound infection, controversy remains around the role of wound dressings in preventing infection. A wide variety of wound dressings are available ranging from simple to complex and some (complex) dressings may interact with the wound to improve healing. However, whilst application of wound dressings is standard practice following surgery in adults, it is rare to apply dressings to wounds in surgery in children. There is no evidence to suggest that covering surgical wounds with dressings reduces the risk of wound infection, or that any particular wound dressing is more effective than another. The evidence, however, is poor, and most studies are small and had faults. Improvements in the way that wound infection is defined and measured are also required, as the current methods vary and lack good agreement. This study involves interviews with health professionals and patients, with the aim to understand current practice in relation to dressings for particular procedures, and to explore views and acceptability about types of dressings and/or not using a dressing. Patients and health professionals are also asked their views on the questionnaires currently available to measure wound infections and what additional issues the questionnaires should include.

Who can participate?
Surgeons, nurses, midwives and patients can take part if they are involved in the care and management of patients undergoing non-emergency abdominal, obstetric or paediatric surgery. Patients are eligible if they are aged 18 or over and are undergoing non-emergency abdominal surgery or non-emergency obstetric surgery (caesarean section).

What does the study involve?
Participants may be asked to be involved in one or more of the following interviews:
1. One-to-one research interviews are undertaken with participants (staff and patients) to understand current idea on dressing use in surgery and to explore attitudes towards a study of dressing type.
2. Semi-structured interviews (staff and patients) are carried out to explore if there were any

surgical site infections, the main problems encountered and the signs and symptoms relevant to them. Participants are asked to comment on a questionnaire developed by the research team. The study team discusses the findings to inform the creation of two new measures (one for staff to complete and one patient-reported measure).
3. The new questionnaires are pre-tested (patients and staff). They are asked to complete the measure developed and comment on their understanding of each item. The wording, format and rating for possible items are then discussed by the research team and suggested improvements or alternatives to those used in existing measures are sought.

What are the possible benefits and risks of participating?
Some people find that taking part in interviews helps them talk through their views and experiences, and that this can be helpful for them. The information from the study will be very helpful to the NHS and to future patients needing operations that carry a risk of wound infection that might be influenced by the use of wound dressings. No risks are expected for participants. However, it is possible that patients may be upset by being asked to talk about their experiences of surgical site infections and wound dressings. If this occurs the clinical team are contacted. Participants are reminded that they can end the interview and/or withdraw from the study at any time.

Where is the study run from?
1. University Hospitals Bristol NHS Foundation Trust (UK)
2. North Bristol NHS Trust (UK)
3. University Hospitals Birmingham NHS Foundation Trust (UK)
4. Birmingham Children's Hospital NHS Foundation Trust (UK)
5. Sandwell and West Birmingham Hospitals NHS Trust (UK)
6. Birmingham Women's NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run?
June 2014 to May 2015

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

Who is the main contact?
Miss Lucy Ellis
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 12/200/04

Study information

Scientific Title
The Bluebelle Study: a feasibility study of complex, simple and absent wound dressings in elective surgery: Phase A

Study objectives
There are no specific hypotheses for this qualitative study. Instead, the study aims to explore the views of healthcare professionals and patients about the use of surgical wound dressings (complex, simple or no dressing) after common operations. The study will also investigate ways to improve the monitoring of wound sites and the diagnosis of wound infections.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Camden & Islington ethics committee, 10/04/2014, ref: 14/LO/0640

Study design
Qualitative design including interviews and questionnaires

Primary study design
Observational

Secondary study design
Multi-centre

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Wound infection

Interventions
This is non-interventional study. All interviews will take between 30-45 minutes and there is no planned follow up. Interviews to explore participant perspectives on wound dressing will include questions focusing on participant background details, experiences of wound care (patients) /dressing usage (healthcare professionals), views about the use of 'no dressings' and perspectives on a study of dressing type. Participants who are interviewed to explore experiences of surgical site infection will be asked to complete and comment on modified versions of the surgical wound healing and ASEPSIS post-discharge questionnaires. Participants taking part in the cognitive interviews will be asked to complete a new measure of surgical site infection which will be developed based on the two questionnaires and participant feedback.

Intervention Type
Other

Primary outcome measure
To establish patient and staff views about wound dressings

Secondary outcome measures
To develop two comprehensive measures of Surgical Site Infection (one for observer completion and the second for patient-reported outcomes) that will be validated in a future pilot randomised controlled trial

Overall study start date
01/06/2014

Completion date
31/05/2015

Eligibility

Key inclusion criteria
1. Adult patients aged 18 or over undergoing elective abdominal surgery, including, but not limited to, gastrectomy for benign and malignant disease, cholecystectomy, small or large bowel resection for benign or malignant conditions, abdominal wall hernia surgery (inguinal, femoral, incisional, epigastric and paraumbilical) or elective obstetric surgery (caesarean section)
2. Consultant surgeons, senior trainees, qualified nurses and midwives involved in the care and management of patients undergoing elective abdominal, obstetric or paediatric surgery

Added 24/11/2014:
An amendment has been approved (18/11/2014) to allow the inclusion of emergency abdominal surgery and emergency caesarean patients who have had an infection.

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
170 interviews

Total final enrolment
102

Key exclusion criteria
1. Paediatric patients
2. Patients unable to give written consent
3. Patients undergoing types of surgery other than abdominal and obstetric surgery
4. Patients having emergency surgery
5. Staff who do not work in field of abdominal, paediatric or obstetric surgery

Date of first enrolment
26/06/2014

Date of final enrolment
31/05/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Bristol NHS Foundation Trust
Bristol
United Kingdom
BS1 3NU

Study participating centre
Birmingham Women's NHS Foundation Trust
Birmingham
United Kingdom
B15 2TG

Study participating centre
North Bristol NHS Trust
Bristol
United Kingdom
BS10 5NB

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Birmingham
United Kingdom
B15 2TH

Study participating centre
Birmingham Children's Hospital NHS Foundation Trust
Birmingham
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B4 6NH

Study participating centre
Sandwell and West Birmingham Hospitals NHS Trust
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B71 4HJ

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The trialists have plans to submit a number of papers for publication in the early part of 2015. These include results from the case studies performed in Phase A and a conceptual and literature work performed about the definitions of dressings and 'no dressings'. They will also submit a protocol paper for the next phase of the study (Phase B) which will be a pilot randomised trial.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/09/2016		Yes	No
Results article	results	01/08/2019	09/08/2019	Yes	No
HRA research summary			28/06/2023	No	No