ISRCTN17599457 https://doi.org/10.1186/ISRCTN17599457

Single use negative pressure dressing for reduction in surgical site infection following emergency laparotomy

Submission date
24/09/2018

Recruitment status
No longer recruiting

Registration date
28/09/2018

Overall study status
Completed

Last Edited
28/01/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Emergency abdominal operations are performed for a variety of life threatening indications, including bowel blockages or perforations, traumatic injuries and major infections. Patients are left with large wounds on the abdomen, at least 1 in 4 of which will become infected. These surgical site infections (SSIs) are painful and take longer to heal, often resulting in a longer hospital stay and greater need for further wound care in the community. In an already unwell patient, development of an SSI can contribute to other major medical complications or even death. Single use negative pressure dressings (SUNPDs) are a special type of closed wound dressing that have recently been developed. They provide gentle suction to the closed wound and may help prevent development of an SSI. Negative pressure dressings are already used for some types of wounds and have been proven to be safe. However, they are more expensive so we need to be sure that that they are effective in reducing SSI before widespread uptake can be recommended within the NHS. This study aims to test whether the use of SUNPDs can reduce rates of SSI after emergency surgery on the abdomen.

Who can participate?
Patients aged 16 and over undergoing emergency abdominal operations

What does the study involve?
Participants are randomly allocated to receive either the new SUNPD dressings or standard dressings to establish whether they are effective in reducing SSI rates. The number of SSIs and the overall costs of treatment are compared between the two groups and the acceptability of the dressings to both patients and health professionals is assessed.

What are the possible benefits and risks of participating?
There are no guaranteed direct benefits involved with participating in this study but the SUNPD dressings could be shown to be more effective than standard dressings in preventing wound infections. The risks associated with the SUNPD dressing are the same as with any dressing after surgery. There is a small risk of a skin reaction or allergy to the dressing, which might cause redness, itching, swelling or pain over the skin next to the dressing. No other risks are known.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
November 2017 to August 2021 (updated 21/01/2021, previously: July 2021)

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

Who is the main contact?
James Brown, sunrrise@trials.bham.ac.uk

Study website
https://www.birmingham.ac.uk/SUNRRISE/

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CPMS 36516, ACTRN12619000496112

Study information

Scientific Title
Single Use Negative pRessure dressing for Reduction In Surgical site infection following Emergency laparotomy

Acronym
SUNRRISE

Study objectives
This study aims to test whether the use of a new type of active wound dressing (Single Use Negative Pressure Dressings 'SUNPDs') can reduce rates of wound infection (also called surgical site infection or 'SSI') after emergency surgery on the abdomen.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, 17/09/2018, ref: 18/YH/0322
2. Scotland A Research Ethics Committee, 10/07/2019, ref: 19/SS/0065
3. South Western Sydney Local Health District HREC, 01/03/2019, ref: SWS HREC EC00265

Study design
Randomised; Interventional; Design type: Treatment, Device

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Surgical wound infection

Interventions
Current intervention as of 17/09/2020:
Patients in the UK and Australia will be identified as possible participants by the surgical team as they are assessed during their admission to hospital. It is likely to be the surgical registrar that identifies the patient but it may be any member of the surgical team from Foundation Year 1 doctor to Consultant.

The patient will be approached at the time that the decision to operate is made. Patients will be given a Patient Information Sheet and the trial will be discussed with them. The dressings will be fully explained and the patient will be given plenty of opportunity to ask questions. The principle of the dressings is simple to understand and our patient focus group believes that patients will be able to understand the trial concept despite the acute nature of their illness and impending surgery.

If the patient agrees to participate in the trial, they will be asked to sign a consent form. They will then undergo an operation as decided by the clinical team. The involvement in this research will have no bearing on the choice or method of operation. As long as the patient fulfils the inclusion criteria, the patient will be randomised to either a SUNPD or a standard dressing at the end of the operation. It is important that this randomisation occurs once the skin has started to be closed. This is to prevent a change in the method of skin closure once it is known which arm the patient is going to be allocated to. When the skin is closed, either a standard dressing or a SUNPD will be applied.

Patients will then undergo their normal pathway of care with no change in usual practice until post-operative day 7 or discharge (whichever is earlier) when the SUNPD will be removed and replace with a standard dressing. The wound will be assessed for the presence of a surgical site infection at 5-10 days or discharge after their operation or discharge (whichever is earlier).

Upon discharge, the patient will be asked to complete a wound diary. This is a simple, tick box sheet that the patient will fill in each day. Every 7 days the diary contains the EQ-5D-5L questionnaire for the patient to fill in. To aid the patient in filling out the diary they will be contacted once a week (by telephone or text) by the research team to remind the patient to fill in the diary and also to provide help if needed in filling it out.
The patient will be asked to undergo a wound review at 30-44 days after their operation for a wound review. This will be by a member of the research team that does not know if the patient had a SUNPD dressing or a standard dressing applied after their operation. The researcher will inspect the wound and ask the patient a few simple questions.

If the wound has healed, the patient will have completed their involvement in the trial. If the patient has a wound that has not fully healed, they will be asked to continue in the trial. If they agree, they will be given a new wound diary and asked to complete until their wound has healed. They do not need to return for another wound check.

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Patients will be identified as possible participants by the surgical team as they are assessed during their admission to hospital. It is likely to be the surgical registrar that identifies the patient but it may be any member of the surgical team from Foundation Year 1 doctor to Consultant.

The patient will be approached at the time that the decision to operate is made. Patients will be given a Patient Information Sheet and the trial will be discussed with them. The dressings will be fully explained and the patient will be given plenty of opportunity to ask questions. The principle of the dressings is simple to understand and our patient focus group believes that patients will be able to understand the trial concept despite the acute nature of their illness and impending surgery.

If the patient agrees to participate in the trial, they will be asked to sign a consent form. They will then undergo an operation as decided by the clinical team. The involvement in this research will have no bearing on the choice or method of operation. As long as the patient fulfils the inclusion criteria, the patient will be randomised to either a SUNPD or a standard dressing at the end of the operation. It is important that this randomisation occurs once the skin has started to be closed. This is to prevent a change in the method of skin closure once it is known which arm the patient is going to be allocated to. When the skin is closed, either a standard dressing or a SUNPD will be applied.

Patients will then undergo their normal pathway of care with no change in usual practice until post-operative day 7 or discharge (whichever is earlier). At this timepoint, the dressing will be removed and the wound will be assessed for the presence of a surgical site infection.

Upon discharge, the patient will be asked to complete a wound diary (See supporting information/documentation). This is a simple, tick box sheet that the patient will fill in each day. Every seven days the diary contains the EQ-5D-5L questionnaire for the patient to fill in. To aid the patient in filling out the diary they will be contacted once a week (by telephone or text) by the research team to remind the patient to fill in the diary and also to provide help if needed in filling it out.

The patient will be asked to return to hospital 30-37 days after their operation for a wound review. This will be by a member of the research team that does not know if the patient had a SUNPD dressing or a standard dressing applied after their operation. The researcher will inspect the wound and ask the patient a few simple questions.

If the wound has healed, the patient will have completed their involvement in the trial. If the patient has a wound that has not fully healed, they will be asked to continue in the trial. If they agree, they will be given a new wound diary and asked to complete until their wound has healed. They do not need to return for another wound check.

Intervention Type
Procedure/Surgery

Primary outcome measure

Current primary outcome measure as of 17/09/2020:
SSI as defined by CDC criteria within 30 days post-operatively. Direct wound assessment will be conducted on day 5-10 post-operation or on discharge (whichever is sooner) and at 30-44 days post-operation by a blinded and trained wound assessor. Wound dairies will also be consulted.

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Previous primary outcome measure:
SSI as defined by CDC criteria; Timepoint(s): Within 30 days post-operatively. Direct wound assessment will be conducted on day 5-7 post-operation or on discharge (whichever is sooner). It will also be performed at 30 days post-operation by a blinded and trained wound assessor.

Secondary outcome measures

Current secondary outcome measures as of 08/10/2021:
1. Length of hospital stay after surgery as measured from the date of index surgery to the date of discharge (this will be reported for UK patients only)
2. Wound complications as graded by Clavien-Dindo scale within 30 days post-surgery
3. Hospital re-admission for wound-related complications within 30 days. These will include SSIs, wound breakdown/dehiscence, seromas, and wound-related pain.
4. Health-related quality of life assessed using the validated Short Form-12 (SF-12) questionnaire at baseline, day 7, and day 30, and the EuroQol-5 Dimension-5 Level (EQ-5D-5L) at baseline, day 7, day 14, day 21, and day 30
5. Pain at the site of the primary laparotomy, assessed using a 10-point visual analogue scale of 1-10 at day 7 and day 30
6. Serious adverse events up to 30 days
7. Cost-effectiveness assessed using a patient diary for patient reported healthcare resource usage. Healthcare usage will be taken directly from the patient diaries and the costs attributable to this will be identified
8. Patient acceptability of use of their dressing via an acceptability score using a 10-point visual analogue scale of 1-10 at day 7, reflecting participant's assessment of the acceptability of having the dressing
9. Health professional's acceptability of use of SUNPD (via a survey of users in the UK only). This will focus on the ease of application of the dressing, the care needed to maintain/monitor the dressing while it is in place and an overall assessment of health professional's experience of the dressing.

Previous secondary outcome measures as of 17/09/2020:
1. Length of hospital stay after surgery as measured from the date of index surgery to the date of discharge
2. Wound complications as graded by Clavien-Dindo scale within 30 days post-surgery
3. Hospital re-admission for wound-related complications within 30 days. These will include SSIs, wound breakdown/dehiscence, seromas and wound-related pain.
4. Health-related quality of life assessed using the validated Short Form-12 (SF-12) questionnaire at baseline, and day 7 and day 30, and the EuroQol-5 Dimension-5 Level (EQ-5D-5L) at baseline, day 7, day 14, day 21 and day 30
5. Pain at the site of the primary laparotomy, assessed using a Likert scale of 1-10 at day 7 and day 30
6. Serious adverse events up to 30 days
7. Cost-effectiveness assessed using a patient diary for patient reported healthcare resource usage. Healthcare usage will be taken directly from the patient diaries and the costs attributable

to this will be identified
8. Patient acceptability of use of their dressing via an acceptability score using a Likert scale of 1-10 at day 7, reflecting participant's assessment of the acceptability of having the dressing
9. Health professional's acceptability of use of SUNPD (via a survey of users in the UK only). This will focus on the ease of application of the dressing, the care needed to maintain/monitor the dressing while it is in place and an overall assessment of health professional's experience of the dressing.

Previous secondary outcome measures:
1. Length of hospital stay after surgery as measured from the date of surgery to the date of discharge
2. Wound complications as graded by Clavien-Dindo scale within 30 days post-surgery
3. Hospital re-admission for wound related complications within 30 days. These will include SSIs, wound breakdown/dehiscence, seromas and wound-related pain
4. Health-related quality of life assessed using the validated Short Form-12 (SF-12) questionnaire at baseline, and day 7 and day 30, and the EuroQol-5 Dimension-5 Level (EQ-5D-5L) at baseline, day 7, day 14, day 21 and day 30
5. Pain at the site of the primary laparotomy, assessed using a Likert scale of 1-10 at day 7 and day 30
6. Serious adverse events up to 30 days
7. Cost-effectiveness assessed using a patient diary for patient reported healthcare resource usage. Healthcare usage will be taken directly from the patient diaries and the costs attributable to this will be identified
8. Patient acceptability of use of their dressing via an acceptability score using a Likert scale of 1-10 at day 7, reflecting participant's assessment of the acceptability of having the dressing
9. Health professional's acceptability of use of SUNPD (via a survey of users at the end of the feasibility phase). This will focus on the ease of application of the dressing, the care needed to maintain/monitor the dressing while it is in place and an overall assessment of health professional's experience of the dressing.

Overall study start date
01/11/2017

Completion date
31/08/2021

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 17/09/2020:
1. All adults undergoing emergency (non-elective) laparotomy
2. Procedures with an incision of at least 5 cm
3. Operations where the skin is closed primarily
4. Patients aged at least 16 years
5. Patients able to provide informed consent, or consultee/representative provides assent /consent if a patient temporarily lacks capacity
6. Patients willing and able to undergo follow-up at 30 days post-op

Previous participant inclusion criteria:
All adults undergoing emergency laparotomy surgery for any surgical indication and via any abdominal incision >5 cm

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 840; UK Sample Size: 520, AUS Sample Size: 320

Key exclusion criteria
1. Aged less than 16 years
2. Permanent/long-term incapacity to consent
3. Procedures with an incision of less than 5 cm
4. Operations where the skin is not primarily closed
5. Abdominal surgery within the preceding 3 months
6. Patient unwilling or unable to attend follow-up visit at around 30 days post-operation
7. Expected return to theatre for reopening of laparotomy wound within 30 days

Date of first enrolment
01/11/2018

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
Australia

England

Scotland

United Kingdom

Study participating centre
Queen Elizabeth Hospital Birmingham
Mindelsohn Way
Birmingham
United Kingdom
B15 2WB

Study participating centre
Birmingham Heartlands Hospital
Bordesley Green East
Birmingham
United Kingdom
B9 5ST

Study participating centre
Sandwell General Hospital
Lyndon
Sandwell
United Kingdom
B71 4HJ

Study participating centre
Stepping Hill Hospital
Poplar Grove
Stockport
United Kingdom
SK2 7JE

Study participating centre
Wythenshawe Hospital
Southmoor Road
Manchester
United Kingdom
M23 9LT

Study participating centre
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Royal Bolton Hospital
Minerva Road

Bolton
United Kingdom
BL4 0JR

Study participating centre
Salford Royal Hospital
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
University Hospital Coventry
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
New Cross Hospital
Wolverhampton Road
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Macclesfield District General Hospital
Victoria Road
Macclesfield
United Kingdom
SK10 3BL

Study participating centre
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Blackpool Victoria Hospital
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre
Ipswich Hospital
Turner Road
Ipswich
United Kingdom
CO4 5JL

Study participating centre
Queen's Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Dorset County Hospital
Williams Avenue
Dorchester
United Kingdom
DT1 2JY

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Royal Blackburn Teaching Hospital
Casterton Avenue
Blackburn
United Kingdom
BB10 2PQ

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Norwich
United Kingdom
NR4 7UY

Study participating centre
Warwick Hospital
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre
Peterborough City Hospital
Bretton Gate
Peterborough
United Kingdom
PE3 9GZ

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road
Aberdeen
United Kingdom
Foresterhill Road

Study participating centre
Royal Alexandra Hospital
Corsebar Road
Paisley
United Kingdom
PA2 9PN

Study participating centre
John Hunter Hospital
Lookout Road

New Lambton Heights
Newcastle
Australia
NSW 2305

Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/03angcq70

Organisation
University of Newcastle Australia

Sponsor details
University Drive
Callaghan
Newcastle
Australia
NSW 2308
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researchintegrity@newcastle.edu.au

Sponsor type
University/education

Website
http://www.newcastle.edu.au/

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0416-20045

Funder Name
National Health and Medical Research Council

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 17/09/2020:
The protocol will be made available on the SUNRRISE website (https://www.birmingham.ac.uk/SUNRRISE/). The findings will be published in international medical journals so that they can help patients globally, with links to publications available on the SUNRRISE website.#

Intention to publish date
31/07/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Laura Magill (e.l.magill@bham.ac.uk) and James Brown (j.p.brown.1@bham.ac.uk). Access to available anonymised data may be granted following review.

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Previous publication and dissemination plan:
The PIS and protocol will be made available on the SUNRRISE website (https://www.birmingham.ac.uk/research/activity/mds/trials/bctu/trials/coloproctology/SUNRRISE/investigators/documentation/docs-existingcentres.aspx) once the website is live and they have been approved. The findings will be published in international medical journals so that they can help patients globally.

IPD sharing statement
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Laura Magill (e.l.magill@bham.ac.uk). Access to available anonymised data may be granted following review.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/12/2020	21/01/2021	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No
Results article		27/01/2025	28/01/2025	Yes	No