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Surgical wounds healing by secondary intention

Submission date
10/12/2015

Recruitment status
No longer recruiting

Registration date
10/12/2015

Overall study status
Completed

Last Edited
20/09/2023

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
More than ten million operations happen in the UK every year. Many operation require a cut to be made in the body through which the surgery can be performed (surgical incision), and these cuts are often closed by a surgeon using stitches or staples. In some cases however, surgical wounds may break open or may be left to heal from the bottom up (open wounds). Wound dressings are commonly used to protect wounds from infection and help the healing process, however the type of dressing that is most effective is widely debated. Negative pressure wound therapy (NPWT) is a technique which involves applying gentle suction to the surface of the wound as it heals. This generally involves a specially designed, sealed dressing being applied to the wound, which is connected to a vacuum pump. The vacuum pump applies continuous negative pressure (sucking) which draws fluid out of the wound and increases blood flow to promote healing. In the future, there are plans to set up a large study to find out which treatment works best: wound dressings or negative pressure wound therapy. This study will take place first to make sure a large study would be possible and would give us the answers needed.

Who can participate?
Adults with open wounds following surgery which are suitable for NPWT.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group receive negative pressure wound therapy (NPWT). Participants in the second group receive usual care which is likely to be wound dressings. Participants in both groups are followed up for three months. This includes weekly or fortnightly assessments with the research nurse to document wound changes, using photographs and a tracing of the wound. Participants are also asked to complete short questionnaires at 2 weeks, 1 month and 3 months which include, at most, an assessment of pain, health and wellbeing, quality of life and medical resource use. Weekly text messages are also be sent to request information from participants regarding their current pain levels in relation to their surgical wound.

What are the possible benefits and risks of participating?
There is no direct benefit to the participants taking part in this study. NPWT and wound dressings are often used in clinical care and therefore the associated risks are minimal. Use of

NPWT should not be uncomfortable, however continued monitoring will be completed as per clinical practice. Side effects, although uncommon, will also be monitored during the study to assess patient safety.

Where is the study run from?
Three NHS hospitals in the Yorkshire area (UK)

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

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

Who is the main contact?
Miss Catherine Arundel

Study website
http://www.york.ac.uk/healthsciences/research/trials/trials/swhsi/

Contact information

Type(s)
Public

Contact name
Miss Catherine Arundel

Contact details
York Trials Unit
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YO10 5DD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20202

Study information

Scientific Title

Surgical Wounds Healing by Secondary Intention (SWHSI): a pilot randomised controlled trial comparing negative pressure wound therapy and usual care for surgical wounds healing by secondary intention

Acronym
SWHSI

Study objectives
More than ten million operations happen in the UK every year. Many operations need a cut to be made and these cuts are often closed by a surgeon using stitches or staples. In some cases however the wounds may break open or may be left to heal from the bottom up.
Dressings or a vacuum pump (called negative pressure wound therapy) are often used to protect the open wound and help it to heal, but we are not sure which of these methods is best to use. In the future, we plan to set up a large trial to find out which treatment works best. This study will take place first to make sure a large study would be possible and would give us the answers we need it to.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire and Humber – Leeds East Research Ethics Committee, 08/10/2015, ref: 15/YH/0370

Study design
Pilot feasibility randomized parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Topic: Surgery; Subtopic: Surgery; Disease: All Surgery

Interventions
Participants are randomly allocated to one of two groups.

Group 1: Participants are treated using negative pressure wound therapy (NPWT). This is a vacuum pump which applies gentle suction to a wound. This study will use two types of product

routinely used in acute and community settings in Hull and Leeds (VAC (KCI) and Renasys (Smith and Nephew) both of which are CE marked devices. NPWT will be delivered as per normal practice. The only requirement is that use of NPWT is clinically appropriate.

Group 2: Participants are treated using usual care. This is likely to include a dressing in contact with the wound and a secondary dressing over that. The frequency of dressing changes will continue as per standard practice.

Participants in both groups are followed up on a weekly or fortnightly basis for a duration of 3 months by the research nurse to assess changes to the wound.

Participants in both groups will be asked to complete short questionnaires at 2 weeks, 1 month and 3 months which include, at most, an assessment of pain, health and wellbeing, quality of life and medical resource use. Weekly text messages will also be sent to request information from participants regarding their current pain levels in relation to their surgical wound.

Intervention Type
Other

Primary outcome measure
Time to healing is assessed by clinical assessment of the wound on a weekly basis with date of healing recorded when clinical assessment is that the wound has full epithelialisation and wound healing treatments have ceased.

Secondary outcome measures
Assessment of data collection methods for a larger study are assessed on an ongoing basis throughout the study duration.

Overall study start date
24/11/2015

Completion date
31/05/2016

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Receiving care from either within Hull and East Yorkshire, Leeds Teaching Hospitals or from Leeds Community Healthcare NHS Trusts
3. Surgical Wounds Healing by Secondary Intention (SWHSI) who could reasonably be treated with either NPWT (Negative Pressure Wound Therapy) or wound dressings, where SWHSI is defined as an open surgical wound not healing by primary intention but from the 'bottom up'
4. The wound should be considered ready for NPWT treatment (i.e. Contain at least 80% viable tissue or have only a very thin layer of slough requiring no further debridement)
5. The patient should be receiving adequate nutrition, as assessed by the senior nurse responsible for nursing care
6. Patients who are able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50; Description: Team advised sample size is 50-80

Key exclusion criteria
1. Inability to provide informed consent
2. People with very limited life expectancy e.g. undergoing end stage palliative care
3. Active systemic infection at baseline, defined by clinical and/or laboratory assessment
4. People already receiving Negative Pressure Wound Therapy (NPWT) (or who have received NPWT on their current surgical wound healing by secondary intention (SWHSI))
5. People who have received NPWT whilst in theatre for the surgery relating to their SWHSI
6. People without adequate haemostasis and who are at risk of bleeding
7. People with the following wound characteristics:
7.1. Presence of unclear undermining in the wound cavity, precluding the use of topical negative pressure therapy (i.e., the deepest point of the wound cannot be measured)
7.2. Necrotic tissue and/or eschar present
7.3. Malignant tissue in the wound
7.4. Wounds involving exposed blood vessels and/or organs, anastomotic sites and/or nerves (including the "open abdomen" where the abdominal fascia is open)
7.5. Wounds situated where, in the opinion of the treating clinician, a vacuum seal cannot be obtained
7.6. Chronic wounds such as pressure ulcers or foot ulcers that were non surgical in origin but which have been surgically debrided (we regard these as a very different subgroup)
7.7. People who are unwilling to have photographs taken of their wound
7.8. People who are currently participating in another research study or who have participated within the last 4 weeks

Date of first enrolment
24/11/2015

Date of final enrolment
31/05/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hull Royal Infirmary
Hull and East Yorkshire NHS Hospitals Trust
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust

Sponsor details
James Illingworth
Hull and East Yorkshire Hospitals NHS Trust
Research & Development Office
Castle Hill Hospital
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England
United Kingdom
HU16 5JQ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01b11x021

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
The results of this study will be fully reported in an open access journal. The study report will also be sent to the Cochrane Wounds Group so that trial data can be used in a meta-analysis. Results will also be included in a final report for the funders of this associated programme.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/11/2016		Yes	No
Results article	results	23/04/2018	29/01/2019	Yes	No
Other publications	feedback from research nurses	01/11/2020	08/09/2020	Yes	No
Funder report results		01/09/2020	04/01/2023	No	No
HRA research summary			20/09/2023	No	No