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Postoperative treatment of perianal abscess cavities: comparing the use of internal wound packing to external dressings

Submission date
23/10/2017

Recruitment status
No longer recruiting

Registration date
01/11/2017

Overall study status
Completed

Last Edited
08/08/2022

Condition category
Digestive System

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

Plain English summary of protocol

Current plain English summary as of 19/07/2019:
Background and study aims
A perianal abscess is an infection close to the back passage (anus). It occurs in thousands of UK patients every year. Standard treatment is a small operation under general anaesthetic when an opening is made in the abscess to let out the infection. The usual treatment is then to place a dressing into the wound (packing). The wound pack is changed every one to two days. Packing has traditionally been used as it is thought to aid healing. However, packing wounds is painful and a small study has suggested that packing may not help wound healing. The aim of this study is to answer whether simple dressings on the wound surface are better than traditional packing into the wound on patients after drainage of a perianal abscess.

Who can participate?
Adults aged 18 and older who are undergoing surgical incision and drainage of a primary perianal abscess.

What does the study involve?
All participants undergo the operation they require to incise and drain their perianal abscess. This cavity will have an internal dressing placed into it at the end of the surgery to help reduce bleeding. This is standard practice and would occur outside of this study. Participants are then randomly allocated to one of two groups. Those in the first group then have the removal of the internal dressing (packing) after 24 hours and continuing dressings provided for over the wound only. No internal dressings will then be used. Those in the second group have the change of the internal dressing (packing) after 24 hours and on-going regular changes of the internal dressing (packing) in the community (standard treatment). All participants are asked to complete a diary over the first 10 days to record their pain, quality of life and comments at various steps during the treatment of the wound. Additional diary entries are completed at 14 and 21 days after the operation. Patients are also contacted by phone to assess whether they have returned to work or normal function. All participants attend an outpatient appointment at four weeks, eight weeks (only if the wound has not healed) and 26 weeks after the procedure to assess the wound and look for evidence of a fistula (a tunnel under the skin from the back passage which can

contain pus and lead to further perianal abscesses and infection). Patients complete a questionnaire four, eight and 26 weeks after their operation to see whether they are experiencing any long-term pain in relation to their original surgery. Participants' hospital records are accessed from the start of the study until six months after the study ends in order to capture information on any further wound-related input from healthcare services outside of the original hospital admission.

What are the possible benefits and risks of participating?
There are no confirmed disadvantages to not using internal dressings in the post-operative abscess cavity but the treatment has not been widely researched so it is an area of uncertainty. In some countries perianal abscesses are managed with no wound packing. It has been suggested that not packing the abscess cavity may reduce the drainage of pus from the wound and allow the skin to heal over the cavity. If this were the case it may increase the risk of future perianal abscess and the risk of fistula formation. However, there is no available data to confirm or refute this suggestion. Some patients can find changing the internal dressing painful and may find the regular visits with the practice/district nurse inconvenient. Those patients assigned to the non-packing arm may experience a reduction in dressing-related pain and more convenient treatment. Being a part of the study means all patients will have closer follow-up after their procedure than is normally provided.

Where is the study run from?
This study is being run by Liverpool Clinical Trials Unit (UK) and takes place in hospitals in the UK.

When is the study starting and how long is it expected to run for?
April 2017 to February 2020 (updated 11/06/2019, previously: July 2020)

Who is funding the study?
NIHR Central Commissioning Facility (CCF) (UK)

Who is the main contact?
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Previous plain English summary:
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Who is the main contact?
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Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

Protocol serial number
35187

Study information

Scientific Title
The impact of postoperative Packing of Perianal Abscess Cavities: a multicentre randomised controlled trial

Acronym
PPAC2: Packing of Perianal Abscess Cavities 2

Study objectives
The aim of this study is to determine if the use of simple dressings on the wound surface will result in reduced post-operative pain and improved quality of life with no increase in rate of recurrent abscess or fistula-in-ano following incision and drainage of perianal abscess when compared to traditional, internal packing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West – Greater Manchester West Research Ethics Committee, 08/09/2017, ref: 17/NW /0529

Primary study design
Interventional

Study design
Randomised; Both; Design type: Screening, Surgery, Health Economic

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgery

Interventions
Patients presenting acutely with a primary perianal abscess who require surgical incision and drainage are randomised 1:1 post-operatively to either:

Arm A) Packing:
Participants in this group have their perianal abscess cavity internally packed as per normal practice.

Arm B) Non-packing:
Participants in this group have a pack placed in theatre as per normal practice, at dressing change the pack is removed and an external application of dressings applied to their perianal abscess cavity.

All patients complete a baseline health related quality of life (HRQOL) questionnaire, followed by daily pain diaries and HRQOL questionnaires until day 10, then again on days 14 and 21. Return to work is established via telephone interviews at seven, 14 and 21 days.

All participants undergo clinical assessment of healing, fistula-in-ano and abscess recurrence at four, eight (if not already healed at week four) and 26 weeks. Chronic pain is assessed at four, eight and 26 weeks. Clinical follow-up ceases at week 26. Hospital admissions for fistula-in-ano and perianal abscess recurrences str obtained from central, NHS registries from weeks 26 to 52.

Participants' hospital records are accessed from the start of the study until six months after the study ends in order to capture information on any further wound-related input from healthcare services outside of the original hospital admission.

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
Wound-related pain (worst pain during previous 24 hours) is measured using patient reported 100mm Visual Analogue Score (VAS) where 0 represents “no pain” and 100 represents “worst pain possible” over the first 10 post-operative days.

Key secondary outcome(s)
1. Pain at dressing change is assessed using a 100mm VAS at days 1-10, day 14 and day 21
2. Health related quality of life are measured using the EQ-5D-5L descriptive system at baseline, days 1-5, and on day 7, 14 and 21
3. Health utility is measured using the EQ-5D-5L descriptive system at baseline, days 1-5, and on day 7, 14 and 21
4. Patient satisfaction with wound management is measured using a five point Likert Scale on day 10
5. Rate of wound healing (complete epithelialization) is measured via clinical examination at four and eight weeks
6. Post-operative fistula-in-ano measured via clinical examination at four, eight and 26 weeks and via hospital episode statistics between week 26 and week 52
7. Abscesses recurrence (after healing) is measured via clinical examination at four, eight and 26 weeks and via hospital episode statistics between week 26 and week 52
8. Bleeding requiring transfusion or return to theatre is measured via clinical examination until week 26
9. Chronic post-surgical pain is measured using the Brief Pain Inventory – short form at weeks 4, 8 and 26
10. Resource use (including dressing, health professional contact time, hospital admission, time to return to work or normal function, analgesic use) is measured up to week 52 via telephone interviews, pain diaries, hospital episodes statistics
11. Cost (applied to resource use data above)
12. Patient assessment of the method of pain control using the Patient Global Assessment of the method of pain control at days 1-10, day 14 and day 21

Completion date
14/02/2020

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Undergoing surgical incision and drainage of a primary perianal abscess

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
433

Key exclusion criteria
Current participant exclusion criteria as of 16/07/2019:
1. Suspected inflammatory bowel disease.
2. Fournier's Gangrene.
3. Horseshoe (bilateral) abscess.
4. Fistula-in-ano.
5. Multiple abscesses.

Previous participant exclusion criteria:
1. Suspected inflammatory bowel disease
2. Fournier's Gangrene
3. Horseshoe (bilateral) abscess

Date of first enrolment
30/11/2017

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 2QQ

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

Study participating centre
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Broomfield Hospital
Court Road
Broomfield
Essex
Chelmsford
United Kingdom
CM1 7ET

Study participating centre
Countess of Chester Hospital
Liverpool Road
Chester
United Kingdom
CH2 1UL

Study participating centre
Derriford Hospital
Derriford Road
Plymouth
United Kingdom
PL6 8DH

Study participating centre

Furness General Hospital
Cumbria
United Kingdom
LA14 4LF

Study participating centre
Glan Clwyd Hospital
Sarn Lane, Rhyl, Denbighshire
Bodelwyddan
United Kingdom
LL18 5UJ

Study participating centre
Homerton Hospital
London
United Kingdom
E9 6SR

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

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

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

Study participating centre
North Tyneside General Hospital
Rake Lane
Tyne and Wear
North Shields
United Kingdom
NE29 8NH

Study participating centre
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Queen Elizabeth The Queen Mother Hospital
St Peters Road
Margate
United Kingdom
CT9 4AN

Study participating centre
Royal Alexandra Hospital
Corsebar Road
Renfrewshire
Paisley
United Kingdom
PA9 2PN

Study participating centre
Royal Blackburn Hospital
Haslingden Road Lancashire
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Royal Bolton Hospital
Minerva Road

Farnworth
United Kingdom
BL4 0JR

Study participating centre
Royal Devon and Exeter Hospital
Barrack Road
Devon
Exeter
United Kingdom
EX2 5DW

Study participating centre
Royal Free Hospital
Pond Street
Hampstead
United Kingdom
NW3 2QG

Study participating centre
Royal Glamorgan Hospital
Llanistrant
Rhonda Cynon Taff
Ynysmaerdy
United Kingdom
CF72 8XR

Study participating centre
Royal Gwent Hospital
Cardiff Road
Newport
United Kingdom
NP20 2UB

Study participating centre
Royal Lancaster Infirmary
Ashton Road
Lancashire
Lancaster
United Kingdom
LA1 4RP

Study participating centre
Royal Preston Hospital
Sharoe Green Lane
Preston
United Kingdom
PR2 9HT

Study participating centre
Royal United Hospital
Hillview Lodge
Coombe Park
Bath
United Kingdom
BA1 3NG

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

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

Study participating centre
Trafford General Hospital
Moorside Road
Davyhulme
Manchester
United Kingdom
M41 5SL

Study participating centre
Queen Elizabeth Medical Centre
Edgbaston
Birmingham
United Kingdom
B15 2TH

Study participating centre
Victoria Hospital
Hayfield Road
Kirkaldy
United Kingdom
KY2 5AH

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

Study participating centre
Wrexham Maelor Hospital
Croesnewydd Road
Wrexham
United Kingdom
LL13 7TD

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

Study participating centre
Yeovil District Hospital
Higher Kingston
Somerset
United Kingdom
BA21 4AT

Study participating centre
Ysbyty Gwynedd (Bangor) Hospital
Penrhosgarnedd
Gwynedd
Bangor
United Kingdom
LL57 2PW

Study participating centre
New Cross Hospital
The Royal Wolverhampton NHS Trust
Wolverhampton Rd
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Morriston Hospital
CAB 3B
Heol Maes Eglwys
Morriston
Swansea
United Kingdom
SA6 6NL

Study participating centre
John Radcliffe Hospital
Surgical Emergency Unit
John Radcliffe Hospital
Oxford University Hospitals NHS Foundation Trust
Headington
United Kingdom
OX3 9DU

Sponsor information

Organisation
Central Manchester University Hospitals NHS Foundation Trust

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/08/2022	08/08/2022	Yes	No
HRA research summary			28/06/2023	No	No