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Hughes Abdominal Repair Trial - abdominal wall closure techniques to reduce incidence of incisional hernias

Submission date	Recruitment status	[X] Prospectively registered
14/06/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/08/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/08/2022	Digestive System	

Plain English summary of protocol

Background and study aims
Incisional hernias are a common complication of abdominal surgery and can be defined as gaps in the wall through which abdominal contents can come through. They can cause patients significant pain, affect body image and also complications, including further major abdominal surgery. This study aims to compare two methods of closing abdominal wounds in the midline. There is the traditional technique of mass closure, involving all layers of the abdominal wall being closed symmetrically at regular points along the wound, and the Hughes repair, which involves closing all layers of the abdominal wall being closed at regular points in a near and far distribution (i.e two sutures close to the midline and two sutures further apart). The idea of the Hughes repair is to distribute tension of the suture closing along different points in the wound and therefore reducing the rate of 'cut through' and development of hernias.

Who can participate?
Patients must be 18 or over, and receive surgical treatment for colorectal cancer which requires a midline incision of 5 cm or more.

What does the study involve?
Patients who agree to take part in the study will be invited to consent to take part in the study. This study aims to compare two methods of closing abdominal wounds in the midline. The patients are randomly allocated to mass closure or Hughes repair. At the end of the study we will compare the two groups for pain, body image concerns and also complications.

What are the possible benefits and risk of participating?
There will be no direct benefits to those taking part. There should be benefits to future patients undergoing abdominal surgery as we think that the Hughes Repair will help to prevent condition that causes significant problems for patients. The patients we have selected to be part of the study will be undergoing CT scans as part of their normal follow up for colorectal cancer so there is no additional radiation exposure and they will also be routinely followed up as standard in all

hospitals, so there is no additional time expenditure for patients or expense for the NHS. The abdomen closure techniques to be used in the study trial are already used in surgery so there is no danger to patients.

Where will the study run from?
The study has been set up to run from the University Hospital of Wales, Cardiff, involving the Welsh Barbers Research Group. Swansea Clinical Trials Unit are conducting the trial on behalf of sponsor Cardiff & Vale University Health Board. Participating centres will be UK wide.

When is the study starting and how long is it expected to run for?
Feasibility phase recruited from October 2013 till February 2014. The pilot phase that will run directly into the main phase started in August 2014 and is expected to recruit until February 2018.

Who is funding the study?
The Health Technology Assessment (HTA) programme (UK)

Who is the main contact?
Professor Jared Torkington
HART@wales.nhs.uk

Study website
http://www.welshbarbers.org/

Contact information

Type(s)
Scientific

Contact name
Prof Jared Torkington

Contact details
Department of General Surgery
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW
-
HART@wales.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Hughes Abdominal Repair Trial - abdominal wall closure techniques to reduce incidence of incisional hernias: a multi-centre pragmatic randomised trial

Acronym
HART

Study objectives
Does Hughes abdominal repair technique change 1-year incisional hernia prevalence relative to usual mass closure of midline laparotomy wounds after colorectal cancer surgery?

Null hypothesis: in these patients Hughes repair will not change 1-year incisional hernia prevalence versus usual mass closure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 3, ref:12/WA/0374

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Available as part of feasibility pack on request

Health condition(s) or problem(s) studied
Abdominal hernia/elective colorectal cancer surgery

Interventions
Participants will be assigned to either Hughes Repair or mass closure repair of midline incisions.

Intervention Type

Procedure/Surgery

Primary outcome measure

Current primary outcome measures as of 21/04/2015:
The primary outcome is the incidence of incisional hernias over one year as assessed by clinical examination of the abdomen.

Previous primary outcome measures:
Incidence of incisionals hernia at one year by:
1. Radiology. The inter recti distance would be measured at a set distance from the symphysis pubis. This would be compared at subsequent CTs postoperatively. The radiologist at the local Multidisciplinary team meeting would be asked to provide an assessment of the presence of incisional hernias and this would be independently assessed.
2. Clinical examination. The clinical presence of a hernia would be assessed either by surgical doctors, who are taught to assess for this as part of their training, or by nurse specialists who either have or will have received training as part of their role. The presence of a hernia can be detected as a palpable mass, usually with a cough impulse, which may or may not cause the patient discomfort or pain.

Secondary outcome measures

Current secondary outcome measures as of 21/04/2015:
1. Two Quality of Life Patient Reported Outcome Measures (PROMs) will be administered at baseline, 30 days, 6 months and 1 year to assess the differences between the two trial groups. The questionnaires used will be SF-12, a shorter version of the original SF36 and the Functional Analysis of Cancer Therapy – Colorectal (FACT-C).
2. Cost-utility analysis of the Hughes Repair in relation to the mass closure in colorectal cancer patients from the perspective of the NHS will be undertaken. Information regarding resource use will be collected, focusing on surgery-specific resources including, but not limited to, open or laparoscopic surgery, duration of surgery, suture details, number and type of complications especially IHs and other SAEs, and subsequent use of health and social care. To measure the subsequent use of health and social care, an existing Client Service Receipt Inventory (CSRI) has been adapted for surgical procedures. A CSRI is a research instrument for collecting data on service use by patients, originally developed for use in Mental Health Services. The unit costs of all these resources will be estimated using published data. Incremental cost-effectiveness ratios (ICER) for IHs avoided will be calculated. SF-6D utilities will be derived from the responses to SF12 questionnaires and used to estimate changes in patients' QoL over time. They will be combined with survival data to estimate the incremental cost per quality adjusted life year (QALY) gained.
3. Data on the incidence of post-operative 'burst abdomen' or full thickness abdominal wall dehiscence will be collected for up to 30 days post operation, as well as details of any repair surgery and the closing sutures used.
4. Data will be collected regarding patient conditions that are considered to be associated with an increased risk of developing hernias, including but not limited to diabetes and obesity. C-POSSUM (Colorectal - Physiological and Operative Severity Score for Understanding Mortality and Morbidity) scores, developed in 1991 and modified in 2004 to assess risk of mortality and morbidity in patients undergoing colorectal surgery, will also be completed. Analysis of these measures will estimate the effect of these factors on IH rates; and whether some patient groups derive greater benefit from the Hughes Repair than others. The presence of other hernias (incisional and non-incisional) as identified by clinical examination and CT will also contribute to the risk assessment of developing a midline incisional hernia following abdominal surgery, as some patients may be more susceptible to developing hernias. Patients who develop post-

operative SSIs are also more likely to develop incisional hernias. Unfortunately SSI is one of the common complications of colorectal surgery. Data will be collected for patients developing SSIs in hospital; the SSIs will be classified into superficial, deep (involving muscle or fascia) or confined to an organ or space. On discharge, patients will be asked to keep a diary (as derived from Williams et al) for up to 30 days post-surgery to record any community-treated wound-related SSIs. Participants will be asked to return the diary at the 30-day visit or return by post, depending on site preference.
5. The prevalence of incisional hernias at one year as measured by clinical examination will be assessed. PROMs will be administered at baseline, 30 days, 6 months and 1 year.
6. The quality of life of patients with or without incisional hernias will be compared over one year. PROMs will be administered at baseline, 30 days, 6 months and 1 year to assess the differences between the two groups.

Previous secondary outcome measures:
Incidence of incisional hernia at further follow up (2-5 years):
1. Complications of surgery. One of the more common complications of colorectal surgery is surgical site infection of the wound. It has been shown that patients with wound infections are more likely to develop hernias following an surgical site infection (SSI). We aim to use a patient diary developed by Professor Leaper to assess SSI in addition to clinical staff reviewing the wound
2. Post operative pain
3. Quality of Life Analysis (SF12 and FACT-C). The Short Form 12 (SF 12) questionnaire is a validated tool for assessment of quality of life. It is a more generic assessment than the FACT-C but has other strengths. It is also a very short questionnaire and has been demonstrated to be valid and results are comparable to the commonly utilised SF36 which is more time consuming for a patient to complete.
4. Cost Analysis at one year and further follow up up (Client Service Receipt Inventory)

Overall study start date
01/07/2013

Completion date
30/09/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 21/04/2015:
1. At screening:
1.1. Patients aged 18 years or older
1.2. Able to give informed consent
1.3. Both standard mass closure and the Hughes repair closure are suitable closing techniques for the patient
1.4. An elective patient for colorectal cancer surgery following full staging investigations including an abdominal CT scan OR an emergency patient with a strong suspicion of colorectal cancer as per CT
2. At point of surgical closure/randomisation:
2.1. Midline abdominal incision (open or laparoscopic assisted/converted)
2.2. Incision of 5 cm or more

Previous inclusion criteria:
1. Patients aged 18 years or older, who are undergoing colorectal cancer surgery with a midline incision (open or laparoscopic assisted).
2. Emergency admissions - providing the patient is able to give informed consent
3. Patients with previous abdominal surgery (non-virgin abdomens)
4. Patients with a previous midline incisional hernia
5. Patients undergoing laparoscopic resections involving midline mini-laparotomies for specimen retrieval

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
830 participants over three phases; feasibility (30 participants), pilot (80 participants) and main phase (720 participants)

Key exclusion criteria
Current exclusion criteria as of 21/04/2015:
1. At screening:
1.1. Unable to provide informed consent
2. At point of surgical closure/randomisation:
2.1. Inserting a mesh as part of abdominal closure
2.2. Undergoing musculofascial flap closure of perineal defect in abdomino-perineal wound closure

Previous exclusion criteria:
1. Patients under 18 years old
2. Pfannenstiel incisions, no midline incisions
3. Patient who are not able to give informed consent

Date of first enrolment
01/07/2013

Date of final enrolment
31/01/2018

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
University Hospital of Wales
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Singleton Hospital
Swansea
United Kingdom
SA2 8QA

Study participating centre
Princess of Wales Hospital
Bridgend
United Kingdom
CF31 1RQ

Study participating centre
Queen’s Hospital
Burton on Trent
United States Minor Outlying Islands
DE13 0RB

Study participating centre
Royal Glamorgan Hospital
Llantrisant
United Kingdom
CF72 8XR

Study participating centre
Glan Cwlyd Hospital
Rhyl
United Kingdom
LL18 5UJ

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

Study participating centre
Yeovil District Hospital
Yeovil
United Kingdom
BA21 4AT

Study participating centre
Royal Blackburn Hospital
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Royal United Hospital
Bath
United Kingdom
BA1 3NG

Study participating centre
Churchill Hospital
Oxford
United Kingdom
OX3 7LE

Study participating centre
Weston General Hospital
Weston Super Mare
United Kingdom
BS23 4TQ

Study participating centre

Macclesfield General District Hospital
United Kingdom
SK10 3BL

Study participating centre
St Mary's Hospital, Imperial
United Kingdom
W2 1PZ

Study participating centre
Ealing Hospital
London
United Kingdom
UB1 3HW

Study participating centre
Royal Bolton Hospital
Bolton
United Kingdom
BL4 0JR

Study participating centre
Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2TH

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

Study participating centre
Maidstone Hospital
Maidstone
United Kingdom
ME16 9QQ

Study participating centre
St Mark’s Hospital
London
United Kingdom
HA1 3UJ

Study participating centre
St Peter’s Hospital
Chertsey
United Kingdom
KT16 0PZ

Study participating centre
Royal Devon & Exeter Hospital
United Kingdom
EX2 5DW

Study participating centre
Doncaster Royal Infirmary
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Hillingdon Hospital
Uxbridge
United Kingdom
UB8 3NN

Study participating centre
Royal Derby Hospital
Derby
United Kingdom
DE22 3NE

Study participating centre

Derriford Hospital
Plymouth
United Kingdom
PL6 8DH

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

Study participating centre
Frimley Park Hospital
Frimley
United Kingdom
GU16 7UJ

Sponsor information

Organisation
Cardiff & Vale University Health Board

Sponsor details
Research and Development Office
Room 2, Floor 2 TB2
UHW
Heath Park
Cardiff
Wales
United Kingdom
CF14 4XW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0489f6q08

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
Planned publication in a high-impact peer reviewed journal

Intention to publish date
30/09/2020

Individual participant data (IPD) sharing plan
The current 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?
Protocol article	protocol	15/09/2016		Yes	No
Interim results article	feasibility trial results	19/12/2017		Yes	No
Results article		01/08/2022	09/08/2022	Yes	No
Results article		08/08/2022	19/08/2022	Yes	No
HRA research summary			28/06/2023	No	No