

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

<b>Submission date</b> 14/06/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 01/08/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/08/2022	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## 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

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Jared Torkington

**Contact details**

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## Additional identifiers

**Protocol serial number**

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

## **Study type(s)**

Treatment

## **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(s)**

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.

## Key secondary outcome(s)

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)

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

## **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  
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LL13 7TD

**Study participating centre**  
**Yeovil District Hospital**  
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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**  
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B15 2TH

**Study participating centre**  
**Countess of Chester Hospital**  
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**Study participating centre**  
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ME16 9QQ

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HA1 3UJ

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**St Peter's Hospital**  
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KT16 0PZ

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**Royal Devon & Exeter Hospital**  
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EX2 5DW

**Study participating centre**

**Doncaster Royal Infirmary**  
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**Study participating centre**  
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PL6 8DH

**Study participating centre**  
**Queen's Medical Centre**  
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**Study participating centre**  
**Frimley Park Hospital**  
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**Sponsor information**

## Organisation

Cardiff & Vale University Health Board

## ROR

<https://ror.org/0489f6q08>

## Funder(s)

### Funder type

Government

### Funder Name

Health Technology Assessment Programme

### Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### 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?
<a href="#">Results article</a>		01/08/2022	09/08/2022	Yes	No
<a href="#">Results article</a>		08/08/2022	19/08/2022	Yes	No
<a href="#">Protocol article</a>	protocol	15/09/2016		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Interim results article</a>	feasibility trial results	19/12/2017		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes

