

# Stoma formation using the sutured trephine annular reinforcement technique

<b>Submission date</b> 24/09/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/01/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/06/2020	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English Summary

### Background and study aims

Parastomal herniation (when the bowel pushes through the muscles surrounding an artificial opening called a stoma and this causes a bulge under the skin) is a common complication following formation of a stoma, occurring in approximately 50% of patients. Although many patients do not suffer from the hernia, approximately 10% require surgical hernia repair, as hernias can cause pain, bag failure, impaired body image and serious/life threatening problems such as bowel obstruction and strangulation of the bowel. Surgical repair of a parastomal hernia is a considerable operation, with its own risks and a high rate of failure (approximately 50%). A technique of using a biological mesh to strengthen the stoma site is currently under investigation and results have shown that reinforcement of the abdominal wall at the stoma site does reduce the incidence of parastomal hernia. This mesh technique is a very costly procedure, so we are aiming to produce the same level of reinforcement of the stoma site using a sutured technique, which will have the same benefits but be less expensive. Comparing both techniques is the aim of this study.

### Who can participate?

All patients over the age of 18, who are not pregnant and require a stoma to be formed for bowel disease as an elective procedure. A total of 100 patients are going to be recruited, with 50 undergoing formation of the stoma by the standard technique and the other 50 undergoing formation of the stoma by the Sutured Trephine Annular Reinforcement Technique (START).

### What does the study involve?

The patients will be informed about the trial and given a patient information sheet by their lead consultant in outpatients when they are listed for surgery. They will then be seen by a member of the research team prior to surgery, so that any questions can be asked and consent can be gained if the patient agrees to trial entry. The patients are then randomly allocated to one of the two techniques (by use of sealed envelopes which are opened just prior to the formation of the stoma in theatre).

Patients who have their stomas reversed will have the occurrence of any parastomal hernia noted by the consultant surgeon during the reversal procedure. For those patients that do not have their stomas reversed, they will be invited to attend outpatients to have the presence of any parastomal hernia assessed clinically by a member of the research team, who does not which

technique has been used.

All patients will be sent Quality of Life questionnaires at 6 months and 30 months.

What are the possible benefits and risks of participating?

There is a risk that there will be no difference to the patients chances of forming a hernia whatever technique is used to form the stoma. However, there is also a chance that one technique may have a lower hernia rate than the other and this may benefit the patient in terms of stoma related complications and stoma function. The process of placing a reinforcing stitch into the stoma hole will take about 10 minutes, so the patients operation may be very slightly longer. However, this should not represent any significant additional risk to the patients health. Sometimes the stoma hole can be a bit tight and this can cause the stoma not to work properly. Very occasionally this requires a further operation to sort it out. However, this is a risk of standard stoma formation and placing the stitch is unlikely to increase this risk.

Where is the study run from?

This study is taking place in Castle Hill Hospital, Hull (UK).

When is the study starting and how long is it expected to run for?

The study started in September 2012 and is anticipated to run for a total of 30 months after the recruitment of the 100th patient (approximately September 2017).

Who is funding the study?

Spire Hospital and University of Hull (UK). The only additional costs incurred during this study are staffing costs. The study is run by research fellows who are already in funded jobs at the Spire Hospital.

Who is the main contact?

Mr Iain Andrew Hunter

[Iain.hunter@hey.nhs.uk](mailto:Iain.hunter@hey.nhs.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Mr Iain Andrew Hunter

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

ASU-IAH-2012.1 START

## **Study information**

### **Scientific Title**

A randomised controlled trial of Sutured Trephine Annular Reinforcement versus standard Technique to assess effect on parastomal herniation

### **Acronym**

START

### **Study hypothesis**

That stoma formation using the sutured trephine annular reinforcement technique leads to reduced parastomal hernia rates.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

NRES Committee Yorkshire and The Humber - Sheffield, 23/04/2012, ref: 12/YH/0127

### **Study design**

Randomised prospective double-blinded controlled trial

### **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

### **Condition**

Parastomal hernias/stoma formation/colorectal surgery

### **Interventions**

Stoma formation via standard trephine formation

Stoma formation via sutured trephine annular reinforcement technique

**Intervention Type**

Procedure/Surgery

**Phase**

Not Specified

**Primary outcome measure**

Parastomal hernia rates at 30 months, or at time of stoma reversal

**Secondary outcome measures**

1. Stoma related complications requiring hospital admission
2. Changes in quality of life assessments over a 30 month period

**Overall study start date**

01/09/2012

**Overall study end date**

01/03/2015

**Eligibility****Participant inclusion criteria**

Participants must:

1. Require an elective stoma due to bowel disease
2. Have given written informed consent
3. Be aged 18 or over
4. Agree to the randomised procedure
5. If of childbearing potential, must have given a negative pregnancy test

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

100

**Participant exclusion criteria**

Patients must not:

1. Be taking part in another clinical trial which directly correlates to this one
2. Have abdominal wall sepsis

3. Be pregnant
4. Be unable to consent to participation
5. Be undergoing refashioning (but not transposition) of the stoma

**Recruitment start date**

01/09/2012

**Recruitment end date**

01/03/2015

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Castle Hill Hospital**

Cottingham

United Kingdom

HU16 5JQ

## Sponsor information

**Organisation**

Hull and East Yorkshire Hospitals NHS Trust (UK)

**Sponsor details**

R & D Department

Office 6, 2nd floor Daisy building

Castle Hill Hospital

Cottingham

England

United Kingdom

HU16 5JQ

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.hey.nhs.uk>

**ROR**

<https://ror.org/01b11x021>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Spire Hospital (UK)

### **Funder Name**

University of Hull (UK)

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration