

# Single port/incision laparoscopic surgery compared with standard 3 port laparoscopic surgery for appendicectomy

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>21/01/2011   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>10/03/2011 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>26/10/2018       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Christiane Pflanz-Sinclair

### Contact details

Centre for Healthcare Randomised Trials (CHaRT)  
Health Services Research Unit  
3rd Floor, Health Sciences Building  
Polwarth Building  
Foresterhill  
Aberdeen  
United Kingdom  
AB25 2ZD

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c.pflanzsinclair@abdn.ac.uk

## Additional identifiers

### Protocol serial number

9282

## Study information

**Scientific Title**

Single port/incision laparoscopic surgery compared with standard 3 port laparoscopic surgery for appendicectomy: a randomised controlled trial

**Acronym**

SCARLESS

**Study objectives**

1. To compare the effectiveness of single port/incision laparoscopic appendicectomy with standard laparoscopic appendicectomy
2. To assess the feasibility of a randomised trial comparing single port laparoscopic to standard laparoscopic surgery for other surgical techniques

**Objectives:**

The primary objective is to compare effectiveness in terms of patient reported outcomes, clinical outcomes, resource use.

The secondary objective is to assess feasibility by quantifying patient eligibility and acceptability, feasibility of blinding participants to the intervention received, surgeon perception of interventions.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Multicentre Research Ethics Committee (MREC) approved on the 8th December 2010 (ref: 10/SO802/77)

**Study design**

Randomised interventional treatment based single centre pilot/feasibility trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Topic: Oral and Gastrointestinal; Subtopic: Oral and Gastrointestinal (all Subtopics); Disease: Gastrointestinal

**Interventions****Interventions:**

Participants will be randomised to either single port/incision laparoscopic surgery (SPILS) or standard 3 port laparoscopic surgery.

Single port/incision laparoscopic surgery (SPILS): single intra-umbilical incision for appendicectomy. A multi channel port or three conventional trocars will be inserted. Conventional laparoscopic instruments will be used but roticulating/curved instruments will be also available for the procedure (if required).

Standard 3 port laparoscopic surgery: Three surgical incisions for appendicectomy (intra /supraumbilical incision to create a pneumoperitoneum and further two incisions located in the left iliac fossa and hypogastrium). Standard laparoscopic instruments will be used for the procedure as per existing hospital protocol.

Patients will be followed-up post-operatively using a 1 to 7 days diary (to be completed while in hospital and home (if patient has been discharged)). Postal questionnaires will be completed by participants at 6 weeks after surgery.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

1. Pain Numerical Rating Scale at days 1 to 7 post surgery
2. Body Image Questionnaire at 6 weeks

### **Key secondary outcome(s)**

1. Patient reported measures:  
Hospital Experience Questionnaire (HEQ) measured at 6 weeks; analgesic usage peri-operatively, Days 1-7 (diary) and at 6 weeks and time to return to normal activities at 6 weeks after surgery.
2. Clinical outcomes:  
Analgesic use; duration of operation (minutes) and complication rates; conversion rates peri-operatively ; infection rates (intra-abdominal and wound) peri-operatively and at 6 weeks; hospital re-admission rates at 6 weeks after surgery; reoperation rates and port-site hernia at 6 weeks after surgery.
3. Feasibility measures:  
Eligible patients per month; proportion formally considered for trial entry; proportion randomised (and reasons why not); proportion who are unaware of their received intervention at 24 hours; proportion of those recruited with complete data set at 6 weeks; surgeons perception of SPILS approach and the suitability of available equipment peri-operatively.

### **Completion date**

31/12/2011

## **Eligibility**

### **Key inclusion criteria**

1. Patients aged 16 years and over, either sex
2. Presenting at Aberdeen Royal Infirmary (ARI)
3. Diagnosed with acute appendicitis and for whom laparoscopic surgical management is judged appropriate

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

16 years

**Sex**

All

**Key exclusion criteria**

1. Patients who have had previous open abdominal surgery through midline incision
2. Patients who have had previous umbilical hernia repair with mesh
3. Patients unable to consent

**Date of first enrolment**

01/01/2011

**Date of final enrolment**

31/12/2011

**Locations****Countries of recruitment**

United Kingdom

Scotland

**Study participating centre**

Centre for Healthcare Randomised Trials (CHaRT)

Aberdeen

United Kingdom

AB25 2ZD

**Sponsor information****Organisation**

University of Aberdeen (UK)

**ROR**

<https://ror.org/016476m91>

**Funder(s)**

**Funder type**

Government

**Funder Name**

Scottish Government Health and Social Care Directorate

**Alternative Name(s)**

SGHSC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

United Kingdom

## Results and Publications

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

Not provided at time of registration

**Study outputs**

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------------------------------------|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               | results                       | 01/01/2015   |            | Yes            | No              |
| <a href="#">Protocol article</a>              | protocol                      | 30/10/2012   |            | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |
| <a href="#">Study website</a>                 | Study website                 | 11/11/2025   | 11/11/2025 | No             | Yes             |