ISRCTN66443895 https://doi.org/10.1186/ISRCTN66443895

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

Submission date 21/01/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/03/2011	**Overall study status** Completed	
Last Edited 26/10/2018	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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?
Results article	results	01/01/2015		Yes	No
Protocol article	protocol	30/10/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes