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

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

Plain English summary of protocol
Not provided at time of registration

Study website
https://w3.abdn.ac.uk/hsru/scarless/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
Can be found at https://w3.abdn.ac.uk/hsru/scarless/Secure/Download/DownloadPage.aspx

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

Secondary outcome measures
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.

Overall study start date
01/01/2011

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

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned sample size: 80; UK sample size: 80

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
Scotland

United Kingdom

Study participating centre
Centre for Healthcare Randomised Trials (CHaRT)
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation
University of Aberdeen (UK)

Sponsor details
Research and Innovation
University Office
King's College
Aberdeen
Scotland
United Kingdom
AB24 3FX

Sponsor type
University/education

Website
http://www.abdn.ac.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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/10/2012		Yes	No
Results article	results	01/01/2015		Yes	No