ISRCTN46101203 https://doi.org/10.1186/ISRCTN46101203

Laparoscopic assisted reversal of ileostomy versus traditional open reversal

Submission date	Recruitment status	[_] Prospectively registered
06/06/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/11/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/10/2013	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NA

Study information

Scientific Title
Laparoscopic assisted reversal of ileostomy versus traditional open reversal: a pilot study

Acronym
LARI

Study objectives
To show that laparoscopic assisted reversal of ileostomy versus traditional open reduces hospital stay and morbidity.
Discharge criteria: having tolerated 2 large meals without nausea/vomiting, passed a bowel motion and adequate pain control on oral analgesia

Please note that as of 14/09/2012, the following changes were made to the record:
1. The scientific title of this trial was changed from "Laparoscopic assisted reversal of ileostomy versus traditional open reversal: a randomised control trial"
2. The target number of participants was changed from 46 to 70

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Adelaide and Meath incorporating the National Children's Hospital (AMNCH) Ethics Committee, Tallaght Hospital approved on the 23rd of February 2010

Study design
Single centre two arm randomised active controlled parallel group 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 contact details below to request a patient information sheet

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

Interventions
Patients undergoing surgery for reversal of ileostomy will be randomised to receive either:
1. Traditional: Ileostomy mobolised from skin. Ileostomy excised followed by side to side anastomosis using GIA. Fascia and peritoneum closed and wound left to heal by secondary intention.

2. Laparoscopic assisted: Ileostomy mobolised from skin. Ileostomy excised followed by side to side anastomosis using GIA. One 5 mm port inserted contra-laterally with pneumoperitoneum. Reversal site checked for any omentum or bowel stuck to sutures. The whole abdominal cavity will be checked for any evidence of metastatic disease. Extra 5mm ports inserted and any adhesions present will be divided as well as any further intervention.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Length of stay

Secondary outcome measures
Morbidity, Diagnostic tool

Overall study start date
01/10/2009

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. Any person with a loop ileostomy who has been passed fit for surgery
2. Age 18-85

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
46

Key exclusion criteria

1. Inability to give informed consent (eg. Dementia)
2. American Society of Anaesthesiologists (ASA) greater than 3

Date of first enrolment
01/10/2009

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
Ireland

Study participating centre
Dept of Surgery
Dublin
Ireland
24

Sponsor information

Organisation
Adelaide and Meath Hospital, Incorporating the National Children's Hospital (AMNCH) (Ireland)

Sponsor details
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Sponsor type
Not defined

ROR
https://ror.org/01fvmtt37

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Adelaide and Meath Hospital, Incorporating the National Children's Hospital (AMNCH) (Ireland) - departmental and personal funds

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?
Results article	results	01/09/2013		Yes	No