

# Laparoscopic assisted reversal of ileostomy versus traditional open reversal

<b>Submission date</b> 06/06/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 11/11/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/10/2013	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## 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

### **Study type(s)**

Treatment

### **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 mobilised 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 mobilised 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(s)**

Length of stay

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

Morbidity, Diagnostic tool

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

85 years

**Sex**

All

**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)

## 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

## 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	01/09/2013		Yes	No