

Stoma or intestinal anastomosis for necrotising enterocolitis of the neonate

Submission date 19/01/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/02/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 06/09/2016	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.ucl.ac.uk/ich/research-ich/surgery/stat-trial>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

09/H0713/58

Study information

Scientific Title

Stoma or intestinal anastomosis for necrotising enterocolitis of the neonate: a multicentre randomised controlled trial

Acronym

STAT Trial

Study objectives

Primary anastomosis after intestinal resection offers significant advantages to neonates with NEC including more rapid recovery of the intestine and therefore shorter duration of time to full feeding.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institute of Child Health/Great Ormond Street Hospital Research Ethics Committee, 07/10/2009, ref: 09/H0713/58

Study design

Multicentre randomised controlled 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Necrotising enterocolitis

Interventions

This will be a multicentre randomised controlled trial which means that 80 neonates (40 in each arm) will be allocated to receive one of these two types of operations which are both valid and

used routinely:

1. Intestine attached to the skin (stoma formation), or
 2. Removal of the diseased gut and joining of the healthy ends (primary anastomosis)
- Both of these types of operation are currently performed for infants with NEC.

Before performing the operation to open the abdomen (laparotomy) parents or care giver of the affected neonate will be asked consent for inclusion in the trial. At laparotomy the surgeon will ascertain the presence of NEC and will assess the extent of the disease. He/she will determine if the infant is eligible (dependent on the listed inclusion/exclusion criteria) and will allocate the child to receive one of the two operations online using the internet or using a sealed envelope as a backup system.

There will be no other research investigations for participants in the study. Clinical information will be collected from medical and nursing records during the stay in hospital and in clinic (if the patient has been discharged from the hospital) at 1, 3 and 6 months after starting the study. The end of follow-up is at 3 years (for neurodevelopmental outcomes).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Duration of parenteral nutrition (days), as this reflects the recovery of intestinal function after NEC and will be affected by complications and/or need for further procedures.

Secondary outcome measures

1. Mortality at 1, 3 and 6 months after randomisation
2. Number and type of surgical procedures performed (including insertion of central venous lines)
3. Hospital stay (days) for survivors and non-survivors
4. Intestinal absorptive function. This will be assessed by measuring:
 - 4.1. Calorie intake (kcal/kg/day) both enterally and parenterally 1 month and 6 months after randomisation
 - 4.2. Weight gain at 1 month and 6 months after randomisation
 - 4.3. Time (days) to full enteral feeding
 - 4.4. Requirement for medication to slow intestinal transit time
5. Intestinal complications:
 - 5.1. Stricture (of either anastomosis or remaining intestine, confirmed by a contrast study and/or histology)
 - 5.2. Anastomotic leak
 - 5.3. Prolapse of stoma
 - 5.4. Stoma necrosis
 - 5.5. Intestinal obstruction
 - 5.6. High output stoma
 - 5.7. Recurrence of NEC
6. Wound complication (infection, incisional hernia, dehiscence)
7. Days on antibiotics, incidence of sepsis (positive blood culture), intra-abdominal abscess requiring drainage or reoperation
8. Intraventricular haemorrhage (ultrasound scan of the brain at enrolment in the trial and 2

weeks after randomisation). Intraventricular haemorrhages will be graded (grade I to IV) according to their extent and severity.

9. Respiratory function. This will be assessed by recording the need for assisted ventilation or oxygen dependency at 1 and 6 months after randomisation

10. Cost of hospital treatment

11. Time to death (days)

12. Cause of death (related to abdominal sepsis/not related to abdomen [cardiac anomaly /cerebral haemorrhage/other])

Overall study start date

01/02/2010

Completion date

01/11/2013

Eligibility

Key inclusion criteria

1. Suspected NEC
2. Need for laparotomy based on:
 - 2.1. Radiological signs of intestinal perforation or
 - 2.2. Failure of improvement with medical treatment
3. Aged 0 - 6 months, either sex

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

80

Key exclusion criteria

1. No evidence of NEC (e.g. intestinal volvulus)
2. Focal intestinal perforation (since many surgeons would not perform a stoma)
3. Extensive NEC precluding intestinal anastomosis (intestinal resection will result in short bowel)
4. NEC affecting the colon that cannot be completely assessed because of risk of bleeding
5. Patient's instability during the operation

Date of first enrolment

01/02/2010

Date of final enrolment

01/11/2013

Locations

Countries of recruitment

Canada

England

Italy

Latvia

Netherlands

Serbia

Sweden

United Kingdom

United States of America

Study participating centre

Nuffield Professor of Paediatric Surgery

London

United Kingdom

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Sponsor information

Organisation

Great Ormond Street Hospital for Children NHS Trust (UK)

Sponsor details

Research and Development Office

30 Guilford Street

London

England

United Kingdom

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Sponsor type

Hospital/treatment centre

Website

<http://www.gosh.nhs.uk/research-and-innovation/>

ROR

<https://ror.org/03zydm450>

Funder(s)

Funder type

Charity

Funder Name

Stanley Thomas Johnson Foundation (Switzerland)

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