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Stoma or intestinal anastomosis for necrotising enterocolitis of the neonate

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

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
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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])

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

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

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
United Kingdom

England

Canada

Italy

Latvia

Netherlands

Serbia

Sweden

United States of America

Study participating centre
Nuffield Professor of Paediatric Surgery
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Sponsor information

Organisation
Great Ormond Street Hospital for Children NHS Trust (UK)

ROR
https://ror.org/03zydm450

Funder(s)

Funder type
Charity

Funder Name
Stanley Thomas Johnson Foundation (Switzerland)

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?
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