ISRCTN18282954 https://doi.org/10.1186/ISRCTN18282954

NET (Necrotising Enterocolitis Trial) - primary peritoneal drainage in necrotising enterocolitis: randomised controlled multi-centre trial

Submission date 15/03/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/04/2004	**Overall study status** Completed	
Last Edited 15/11/2013	**Condition category** Digestive System	

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
MREC/02/2/34

Study information

Scientific Title

Acronym
NET

Study objectives
To determine whether primary peritoneal drainage improves the survival and outcome of ELBW infants with perforated necrotising enterocolitis (NEC) or with isolated intestinal perforation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This project has been approved by an independent research ethics committee.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Necrotising enterocolitis or isolated intestinal perforation

Interventions
Primary peritoneal drain or laparotomy.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Survival at 1 and 6 months after randomisation.

Key secondary outcome(s)
1. Time to death (days)
2. Cause of death (related to abdominal sepsis/not related to abdomen [cardiac anomaly/cerebral haemorrhage/other])
3. Hospital stay for survivors and non survivors (days)
4. Intestinal absorptive function. This will be assessed by measuring:
4.1. The calorie intake (kcal/kg/day) both enterally and parenterally 1 month and 6 months after randomisation
4.2. The weight gain at 1 month and 6 months after randomisation
4.3. The duration of parenteral nutrition (days)
4.4. The time to full enteral feeding (days)
5. Long term intestinal complications:

5.1. Intestinal stricture (confirmed by a contrast study and/or histology)
5.2. Persistent entero-cutaneous fistula
6. 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
7. Respiratory function. This will be assessed by assessing the need for assisted ventilation or oxygen dependency at 1 and 6 months after randomisation.

Completion date
20/03/2006

Eligibility

Key inclusion criteria
Extremely low birth weight (ELBW) infants (weight less than or equal to 1000g) with perforated necrotising enterocolitis or isolated perforation.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Bilateral grade 4 intraventricular haemorrhages
2. Previous laparotomy
3. Previous peritoneal drain
4. Recurrent NEC

Date of first enrolment
01/11/2002

Date of final enrolment
20/03/2006

Locations

Countries of recruitment
United Kingdom

England

Australia

Belgium

France

Hong Kong

Ireland

Italy

Japan

Korea, South

Netherlands

New Zealand

South Africa

Spain

Switzerland

United States of America

Study participating centre
Dept of Surgery
London
United Kingdom
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Sponsor information

Organisation
Institute of Child Health and Great Ormond Street Hospital (UK)

ROR
https://ror.org/00zn2c847

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?
Results article	Results	01/07/2008		Yes	No
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