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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

Registration date
13/04/2004

Overall study status
Completed

Last Edited
15/11/2013

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.nettrial.net/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Parent information sheets are available in English (http://www.ich.ucl.ac.uk/ich/html/academicunits/surgery/nettrial/downloads/NET_ParentInfo.pdf) and in German (http://www.ich.ucl.ac.uk/ich/html/academicunits/surgery/nettrial/downloads/NET_ParentInfo_German.pdf).

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 measure
Survival at 1 and 6 months after randomisation.

Secondary outcome measures
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.

Overall study start date
01/11/2002

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

Age group
Neonate

Sex
Both

Target number of participants

208

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
Australia

Belgium

England

France

Hong Kong

Ireland

Italy

Japan

Korea, South

Netherlands

New Zealand

South Africa

Spain

Switzerland

United Kingdom

United States of America

Study participating centre

Dept of Surgery
London
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WC1N 1EH

Sponsor information

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

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Sponsor type
Research organisation

ROR
https://ror.org/00zn2c847

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/07/2008		Yes	No