

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/04/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/11/2013	Condition category Digestive System	<input type="checkbox"/> 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

Contact name

Prof Agostino Pierro

Contact details

Dept of Surgery
Institute of Child Health
30 Guilford St
London
United Kingdom
WC1N 1EH
+44 (0)20 7905 2641
a.pierro@ich.ucl.ac.uk

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

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
United Kingdom
WC1N 1EH

Sponsor information

Organisation

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

Sponsor details

30 Guilford St
London
United Kingdom
WC1N 1EH
+44 (0)20 7905 2641
net@nettrial.net

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