

Early Diagnosis of Necrotising Enterocolitis: a prospective observational multicentre trial in neonates presenting with acute abdomen

Submission date 15/04/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/07/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/05/2009	Condition category Digestive System	<input type="checkbox"/> Individual participant data

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
1

Study information

Scientific Title

Acronym

ED-NEC

Study objectives

As of 11/05/2009 this record was significantly updated due to a change in the sources of funding and subsequent changes to the protocol. All updates can be found under the relevant fields with the above update date. At this time, the dates of the trial were also updated; the initial trial dates were as follows:

Initial anticipated start date: 01/01/2008

Initial anticipated end date: 31/12/2010

Current hypothesis as of 11/05/2009:

To establish biomarkers for necrotising enterocolitis (NEC) among neonates presenting with an acute abdomen.

Initial information at time of registration:

To test the capacity of the routine laboratory parameters C-reactive protein (CRP), differential blood count and blood gas analysis as well as additional novel parameters (fatty acid binding protein, platelet activating factor, markers of innate immunity, coagulation profile) in the early diagnosis of necrotising enterocolitis (NEC) among neonates presenting with an acute abdomen.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval pending as of 11/05/2009

Study design

Prospective observational multicentre trial

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Neonatal intestinal disease

Interventions

Assessment of an acute abdomen possibly due to NEC.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Current information as of 11/05/2009:

Differences of biomarkers between infants with NEC stage II and III and other diseases causing acute abdomen.

Initial information at time of registration:

Outcomes:

Evaluation of the clinical usefulness of promising laboratory parameters for early recognition of NEC among infants with acute gastrointestinal illness.

Endpoints - difference between diagnostic markers between groups:

1. For period one: at the end of period two, when all parameters are measured and statistically analysed (December 2009)
2. For period three: one year following the end of period three (December 2011)

Key secondary outcome(s)

Current information as of 11/05/2009:

1. Correlations between biomarkers and NEC disease severity (mortality, NEC stage, need for inotropic agents, mechanical ventilation, need for surgery)
2. Length of hospital stay

Initial information at time of registration:

Outcomes:

Prospective validation of statistically useful parameters from the first period by subdividing centres into application and non-application of a defined diagnostic algorithm.

Endpoints - prediction of mortality at a given time in either group:

1. Need for additional support with inotropic agents in either group. Will only be assessable during period three: one year following the end of period three (December 2011)
2. Prediction of the maximum disease severity as classified by Bell:
 - 2.1. For period one: At the end of period two, when all parameters are measured and statistically analysed (December 2009)
 - 2.2. For period three: one year following the end of period three (December 2011)

Completion date

31/01/2012

Eligibility

Key inclusion criteria

Current information as of 11/05/2009:

1. Newborns below 36 days of postnatal age
2. Acute abdomen with suspicion of NEC
3. Gestational age below 34 weeks of gestational age (GA)
4. Written parental consent

Initial information at time of registration:

1. Newborns below 36 days of postnatal age
2. Clinical, laboratory and radiological assessment for an acute abdomen possibly due to NEC
3. For the diagnosis of NEC among infants presenting with an acute abdomen, the criteria of Bell, modified by Walsh and Kliegman and adopted by the Vermont Oxford Network:
 - 3.1. The presence of one or more of the following clinical signs:
 - 3.1.1. Feeding intolerance with bilious gastric aspirate or emesis
 - 3.1.2. Abdominal distension
 - 3.1.3. Occult or gross blood in stool (no fissure)

3.2. And one or more of the three following radiographic findings:

3.2.1. Pneumatosis intestinalis

3.2.2. Hepato-biliary gas

3.2.3. Pneumoperitoneum

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

Current information as of 11/05/2009:

1. Age above 35 days of postnatal age
2. Patients that had undergone surgery one week prior to onset of the disease

Initial information at time of registration:

1. Age above 35 days of postnatal age
2. Patients that had undergone surgery one week prior to onset of the disease
3. Focal intestinal perforation consistent with:
 - 3.1. Visual aspect of the bowel at the time of surgery and post-mortem
 - 3.2. Absence of inflammation and coagulative necrosis in histological findings

Date of first enrolment

01/02/2010

Date of final enrolment

31/01/2012

Locations

Countries of recruitment

United Kingdom

Austria

Finland

France

Germany

Netherlands

Poland

Sweden

Switzerland

Study participating centre

Inselspital

Berne

Switzerland

CH-3010

Sponsor information

Organisation

Island Hospital (Inselspital) (Switzerland)

ROR

<https://ror.org/01q9sj412>

Funder(s)

Funder type

University/education

Funder Name

Current information as of 11/05/2009:

Funder Name

University of Berne (Switzerland) - further applications in process

Funder Name

Initial information at time of registration:

Funder Name

Seventh Framework Programme (FP7) European Union Research Funding (Belgium) - In frame for this kind of funding

Funder Name

Further national and international programs, such as:

Funder Name

1. University of Berne (Switzerland)

Funder Name

2. Department of Surgical Paediatrics, Hospital of Berne (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	retrospective collection results:	01/12/2006		Yes	No
Results article	case-control results:	01/11/2008		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