ISRCTN14384676 https://doi.org/10.1186/ISRCTN14384676

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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/07/2007	**Overall study status** Completed	
Last Edited 11/05/2009	**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
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