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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

Registration date
02/07/2007

Overall study status
Completed

Last Edited
11/05/2009

Condition category
Digestive System

[X] 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.ednec.ch

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Multi-centre

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Parent information will be available at http://www.ednec.ch/ as soon as ethical approval is obtained

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 measure
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)

Secondary outcome measures
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)

Overall study start date
01/02/2010

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

Age group
Neonate

Sex
Both

Target number of participants
Added as of 11/05/2009: 50 infants diagnosed with NEC (previously 100)

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
Austria

Finland

France

Germany

Netherlands

Poland

Sweden

Switzerland

United Kingdom

Study participating centre
Inselspital
Berne
Switzerland
CH-3010

Sponsor information

Organisation
Island Hospital (Inselspital) (Switzerland)

Sponsor details
-
Berne
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Sponsor type

Hospital/treatment centre

Website
http://www.insel.ch/

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

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	retrospective collection results:	01/12/2006		Yes	No
Results article	case-control results:	01/11/2008		Yes	No