

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

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

### **Primary study design**

Observational

### **Study design**

Prospective observational multicentre trial

### **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?
<a href="#">Results article</a>	retrospective collection results:	01/12/2006		Yes	No
<a href="#">Results article</a>	case-control results:	01/11/2008		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes