The Long-Term Effects of Neonatal Necrotizing Enterocolitis

Published: 06-07-2011
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To evaluate the bowel function, quality of life and nutritional status in adolescents/adults who experienced an episode of NEC at neonatal age.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal signs and symptoms
Study type	Observational invasive

Summary

ID

NL-OMON35989

Source
ToetsingOnline

Brief title
Long-term NEC

Condition

- Gastrointestinal signs and symptoms
- Neonatal and perinatal conditions

Synonym
inflammatory condition of the bowel

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: long-term, necrotizing enterocolitis (NEC)

Outcome measures

Primary outcome

Bowel function at adolescent/adult age as measured by a questionnaire developed and validated in our center.

Secondary outcome

The secondary study parameters are nutritional status, prevalence of irritable bowel syndrome (IBS), quality of life, and bone mineral density.

Study description

Background summary

Neonatal Necrotizing enterocolitis (NEC) is a gastrointestinal disease mainly affecting premature neonates with a relatively high mortality and morbidity. The literature suggests some deficiencies in vitamin status and bone mineral density associated with intestinal diseases. To date, no information is available regarding the quality of life, bowel function, bone mineral density, and nutritional status in the adolescent/adult age.

Study objective

To evaluate the bowel function, quality of life and nutritional status in adolescents/adults who experienced an episode of NEC at neonatal age.

Study design

Single centre, prospective, descriptive cohort study.

Study burden and risks

Subjects will have the benefit of having their intestinal function, blood parameters (vitamin status etc), and bone mineral density evaluated. The expected burden for the participants is negligible. Patients are asked to fill

in questionnaires regarding functional bowel symptoms, IBS symptoms, quality of life and to fill in dietary records (both groups). They are also asked to visit the outpatient clinic for a nutritional status assessment, blood sampling, and a DEXA scan.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

NEC group: Adolescents/adults with episode of NEC at neonatal age, treated conservatively or surgically in the period January 1, 1980 and December 31, 1995, and informed consent.

Exclusion criteria

Unable to complete the questionnaire.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-12-2011
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	06-07-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL35786.078.11