Follow-up GEEF-study: Behavioral development, school performance, neurocognitive functioning and brain development of very premature (<32 weeks) and/or very low birth weight (<1500 grams) children at school-age, with or without glutamine suppletion after birth

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Observational invasive

Summary

ID

NL-OMON33479

Source
ToetsingOnline

Brief title
Development of very premature and/or VLBW children at school-age

Condition

- Structural brain disorders
- Neonatal and perinatal conditions

- Psychiatric disorders

Synonym
"immature brain development caused by preterm birth", "Prematurity"

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Danone,Danone Research

Intervention

Keyword: Brain-imaging, Development, Follow-up, Prematurity

Outcome measures

Primary outcome

Differences as measured by neurocognitive assessment, behavioural and emotional questionnaires, and school performance. Furthermore, differences in brain structure as determined by sMRI (volumetric parameters of white and grey matter) fMRI (BOLD-signal changes) and DTI (FA-value indicating white matter integrity).

Secondary outcome

Not applicable

Study description

Background summary

Follow-up study of very premature (<32 weeks of gestation) and/or very low birth weight (VLBW, < 1500 grams) infants who participated in the Glutamine Enriched Enteral Feeding-study (GEEF, van den Berg et al., 2004), to determine the effects of glutamine supplementation on later developmental outcomes.

Study objective

The main objective of the study is to provide insight in the developmental problems of very premature and/or VLBW children compared to their term born peers, and to investigate the possible beneficial longitudinal effects of the GEEF intervention on these problems. This will be done by gathering information concerning the neurocognitive performance, behavioural/emotional development, performance at school and brain development (by conducting brain imaging) of very premature and/or VLBW children from the GEEF-intervention study (both glutamine and placebo condition) and term born controls.

Study design

Observational study

Study burden and risks

Each participant will be asked to visit the VU University Medical Center twice. During the first visit of approximately 3 hours including breaks, the neurocognitive assessment (childen) and the questionnaires (parents) will be administrated. During the second visit of approximately 1 hour, brain scanning will be conducted.
For participants, the burden of the neurocognitive assessment is minimal. Experiences from earlier studies with children in this age range have taught us that the proposed length of assessment is feasible. During brain scanning, discomfort can be expected from loud noise and claustrophobia. This discomfort will be minimized by providing ear plugs and close company of a familiar person as much as possible during the procedure. Risks associated with participation are negligible.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV Amsterdam
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Participation with the original GEEF-study (which had the inclusioncriteria: <32 weeks of gestation and/or lower than 1500 grams birth weight).

Exclusion criteria

Deafness or Blindness, which will make the assessment of neuropsychological tasks impossible

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-11-2009

Enrollment:	170
Type:	Actual

Ethics review

Approved WMO Date:	23-09-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL28378.029.09