

Hyperechogenicity of the thalamus and basal ganglia in very preterm infants

Submission date 29/06/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/06/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 08/01/2021	Condition category Nervous System Diseases	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL617, NTR676

Study information

Scientific Title

Hyperechogenicity of the thalamus and basal ganglia in very preterm infants

Study objectives

The principal aim of this research project is to establish the origin of increased echogenicity in the thalamus and basal ganglia (TBG), an ultrasonographic finding frequently encountered in very preterm infants. It is not known whether echodensities (ED) of TBG is a normal maturational phenomenon or a pathological process with consequences for neurological development. ED /TBG may, like transient ED in the frontal white matter, represent normal maturational changes occurring in the thalamus, basal ganglia, and/or the surrounding brain tissue. However, it may also represent damage to the developing brain, like more inhomogeneous ED in TBG in (near) term infants, unilateral or localized ED in TBG in preterm infants, linear and/or punctate ED in TBG in preterm and full term infants, and long-lasting ED in the periventricular white matter in preterm infants do. If so, ED/TBG is an important finding and may be associated with an unfavourable or even poor neurological prognosis. We want to explore whether ED/TBG is a pathological phenomenon or a normal (maturational) phenomenon occurring in the immature brain, and to establish the possible consequences of ED/TBG for short and long term neurological outcome of very preterm infants.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Non-randomized, single centre, parallel group study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Health condition(s) or problem(s) studied

Preterm infants with hyperechogenicity of TBG

Interventions

In all very preterm infants born after a gestational age of less than 32 weeks, serial cerebral ultrasonography (CUS) examinations will be performed according to the standard protocol. All

CUS examinations will be evaluated for the presence of diffuse ED/TBG. This will result in a division of all preterm infants into two groups, i.e. a group of preterm infants with ED/TBG and a group of preterm infants without ED/TBG. All infants (infants with and without ED/TBG) will undergo a single cerebral magnetic resonance imaging (MRI) examination around term date. In addition, they will visit our follow-up clinic around term date and at corrected ages of 12 and 24 months, when their neurodevelopment will be assessed. The results obtained from CUS, MRI and follow-up will be compared between the infants with ED/TBG and the infants without ED/TBG.

The only difference between the two groups of infants is that in one group ED/TBG is detected on CUS, whereas in the other group ED/TBG is not detected. There is no difference between groups in the number of examinations.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The origin and clinical significance of ED/TBG in very preterm infants

Secondary outcome measures

Improvement in the prediction of neurological prognosis of individual preterm infants and the understanding of maturational and pathological processes in the preterm brain

Overall study start date

03/04/2006

Completion date

31/03/2010

Eligibility**Key inclusion criteria**

Infants born after a gestational age of less than 32 weeks in the Leiden University Medical Center between May 2006 - August 2007.

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

140

Total final enrolment

Key exclusion criteria

Congenital anomalies or serious acquired abnormalities of the central nervous system, chromosomal disorders, metabolic disorders, neonatal meningitis or sepsis.

Date of first enrolment

03/04/2006

Date of final enrolment

31/03/2010

Locations**Countries of recruitment**

Netherlands

Study participating centre

Leiden University Medical Center (LUMC)

Leiden

Netherlands

2300 RC

Sponsor information**Organisation**

Leiden University Medical Center (LUMC) (The Netherlands)

Sponsor details

P.O. Box 9600

Leiden

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Sponsor type

University/education

ROR

<https://ror.org/05xvt9f17>

Funder(s)**Funder type**

University/education

Funder Name

Leiden University Medical Center (LUMC)

Funder Name

ZonMw (The Netherlands Organization for Health Research and Development)

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

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	results	01/03/2011	08/01/2021	Yes	No