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Hyperechogenicity of the thalamus and basal ganglia in very preterm infants

Submission date	Recruitment status	[ ] Prospectively registered
29/06/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/06/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/01/2021	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Lara Leijser

Contact details
Leiden University Medical Center (LUMC)
Willem-Alexander Kinder- en Jeugdcentrum
Postzone J6-S
P.O. Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 5262909
L.M.Leijser@lumc.nl

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
Netherlands
2300 RC

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