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A randomised controlled trial of thyroxine in preterm infants under 28 weeks gestation

Submission date	Recruitment status	[_] Prospectively registered
20/03/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/03/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/07/2013	Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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L8 7SS

Additional identifiers

EudraCT/CTIS number
2005-003099-39

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MRC ref: G0501788; LWH0604

Study information

Scientific Title

Acronym
TIPIT (Thyroxine In Preterm Infants Trial)

Study objectives
Thyroxine supplementation given to extreme preterm infants postnatally until 32 weeks postmenstrual age modulates brain development and size, the Hypothalamic-Pituitary-Adrenal axis (HPT) and somatic growth.

More details can be found at: http://www.mrc.ac.uk/ResearchPortfolio/Grant/Record.htm?GrantRef=G0501788&CaseId=6765

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the North West Multicentre Research Ethics Committee (ref: 07/MRE08/37)

Study design
Randomised double-blinded placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Premature infants

Interventions
In the initial phase, infants will receive either intravenous thyroxine or placebo at 8 mcg/kg birth weight/day single daily dose. In the next phase, once enteral feeds are fully established, oral thyroxine or placebo will be given at 8 mcg/kg birth weight/day single daily dose until the baby reaches 32 weeks CGA.

Details of Joint Sponsor:
University of Liverpool
Liverpool
L69 3BX
United Kingdom
Tel: +44 (0)151 794 2000
http://www.liv.ac.uk/

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Thyroxine

Primary outcome measure
The primary outcome will be the width of the sub-arachnoid space measured using cranial ultrasound and head circumference at 36 weeks Corrected Gestational Age (CGA).

Secondary outcome measures
1. Width of the sub-arachnoid space measured using cranial ultrasound at 36 weeks Corrected Gestational Age (CGA)
2. Head circumference at 36 weeks CGA

Overall study start date
01/06/2007

Completion date
01/12/2009

Eligibility

Key inclusion criteria
All infants with gestational age under 28 weeks at birth

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
150

Key exclusion criteria

1. Infants born to mother with known thyroid disease or on antithyroid medications during pregnancy
2. Infants born to mother who are on amiodarone during pregnancy
3. Infants diagnosed with major congenital or chromosomal abnormalities known to affect thyroid function or brain development
4. Maternal death during or within 5 days after childbirth

Date of first enrolment
01/06/2007

Date of final enrolment
01/12/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Reproductive and Developmental Medicine
Liverpool
United Kingdom
L8 7SS

Sponsor information

Organisation
Liverpool Women's NHS Foundation Trust (UK)

Sponsor details
Dr Gill Vernon
R&D Department Manager
Liverpool Women's Hospital
Crown Street
Liverpool
England
United Kingdom
L87SS

Sponsor type
Hospital/treatment centre

Website

http://www.lwh.me.uk/

ROR
https://ror.org/04q5r0746

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
The Newborn Appeal (UK)

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?

Protocol article	protocol	26/03/2008	Yes	No
Protocol article	MRI protocol	30/06/2008	Yes	No
Results article	results	11/07/2013	Yes	No