ISRCTN89493983 https://doi.org/10.1186/ISRCTN89493983

# 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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**Contact details**
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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 |