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A pilot study to inform a randomised controlled trial of iodine supplementation in preterm infants

Submission date 20/05/2005	**Recruitment status** No longer recruiting
Registration date 19/07/2005	**Overall study status** Completed
Last Edited 04/10/2018	**Condition category** Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
2005-002404-42

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A pilot study to inform a randomised controlled trial of iodine supplementation in preterm infants

Acronym
Euthyroid2

Study objectives
1. We aim to determine whether enteral supplementation with iodine is effective in promoting a positive iodine balance in extreme preterm infants who are parenterally fed
2. To determine the efficacy of the oral versus the nasogastric route of iodine supplementation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Transient hypothyroxinaemia

Interventions
Iodine supplementation 30 µg/kg/day versus placebo (sterile distilled water)

Intervention Type
Supplement

Primary outcome measure
Serum T4 levels

Secondary outcome measures

Not provided at time of registration

Overall study start date
01/09/2005

Completion date
30/09/2007

Eligibility

Key inclusion criteria
Infants who are born earlier or at 30 weeks gestation and who mothers are able to give informed consent.

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
44

Key exclusion criteria
Infants born over 30 weeks gestation. Infants will be excluded from the study if their mother is known to be viral hepatitis/HIV positive, or if their mother has problems giving consent because of mental illness or communication difficulties. Infants with serious congenital anomaly will be excluded.

If any infant is found to have hypothyroidism, following routine Guthrie Card screening, they will be excluded from further study and treated with thyroxine.

Date of first enrolment
01/09/2005

Date of final enrolment
30/09/2007

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Dundee
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee (UK)

Sponsor details
Nethergate
Dundee
Scotland
United Kingdom
DD1 4HN

Sponsor type
University/education

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Other

Funder Name
Not provided at time of registration

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	01/07/2014		Yes	No
Results article	results	01/05/2017		Yes	No