

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	☒ Prospectively registered
Registration date 19/07/2005	Overall study status Completed	☒ Protocol
Last Edited 04/10/2018	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

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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Additional identifiers

Clinical Trials Information System (CTIS)

2005-002404-42

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Serum T4 levels

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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**

United Kingdom

Scotland

Study participating centre

University of Dundee

Dundee

United Kingdom

DD1 9SY

Sponsor information**Organisation**

University of Dundee (UK)

ROR

<https://ror.org/03h2bxq36>

Funder(s)

Funder type

Other

Funder Name

Not provided at time of registration

Results and Publications

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	01/05/2017		Yes	No
Protocol article	protocol	01/07/2014		Yes	No