ISRCTN13668937 https://doi.org/10.1186/ISRCTN13668937

A prospective, randomised pilot study in the management of neonates at risk of hypoglycaemia (34 weeks to term) by oral feeding using preterm formula.

Submission date
30/09/2005

Recruitment status
No longer recruiting

Registration date
30/09/2005

Overall study status
Completed

Last Edited
08/04/2014

Condition category
Neonatal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0084144605

Study information

Scientific Title

Study objectives
Preterm formula milk, having a higher calorie density than standard formula, is beneficial in maintaining blood glucose levels in neonates at high risk of hypoglycaemia.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Neonatal Diseases

Interventions
Randomisation of at least 10 in each arm, routine management of cannulation and intravenous glucose or oral feeding of Preterm formula.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The two groups are compared using independent t-tests. So calculating means or proportions per group with 95% Cls for the difference between means or proportions as appropriate. If there

is an element of repeated measures (i.e. if measuring each person more than once) then calculate the area under the curve (AUC) for each group and then compare the AUCs for binary categorical data odds ratios again with 95% CIs, can be used. Somewhere, an arbitrary level of 5% significance (two-tailed) will be assumed. Randomisation will be according to a random numbers table. Even split can not be done with a small sample. Due to small sample, the method of minimisation may be used, when randomising, or randomise using blocks.

Secondary outcome measures
Not provided at time of registration

Overall study start date
05/04/2004

Completion date
04/04/2005

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Neonate

Sex
Not Specified

Target number of participants
Convenience sampling will be used to accrue a minimum sample size of 20 neonates.

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
05/04/2004

Date of final enrolment
04/04/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northern Lincolnshire & Goole Hospitals NHS Trust
Scunthorpe
United Kingdom
DN15 7BH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Northern Lincolnshire and Goole Hospitals NHS Trust (UK), NHS R&D Support Funding

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