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

Protocol serial number
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

Study type(s)
Not Specified

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(s)
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.

Key secondary outcome(s))
Not provided at time of registration

Completion date
04/04/2005

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration