

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	☐ Prospectively registered
		☐ Protocol
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 08/04/2014	Condition category Neonatal Diseases	☐ 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

Primary study design

Interventional

Study design

Randomised controlled trial

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% CIs 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