

Randomised controlled trial of different energy formulas in healthy term infants: effects on later growth, body composition, bone health and cardiovascular?

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/05/2017	Condition category Neonatal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0012154277

Study information

Scientific Title

Randomised controlled trial of different energy formulas in healthy term infants: effects on later growth, body composition, bone health and cardiovascular?

Study objectives

Do differences in early energy intake and growth program fatness and other aspects of health during adolescence?

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

Random Allocation (A) energy formula (B) standard; Cohort observation.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Body composition, bone mass, risk factors for cardiovascular disease (blood lipids, insulin) DXA

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/08/2004

Completion date

31/01/2006

Eligibility

Key inclusion criteria

Healthy term infants

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/08/2004

Date of final enrolment

31/01/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Childhood Nutrition Research Centre
London
United Kingdom
WC1N 1EH

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Great Ormond Street Hospital for Children NHS Trust / Institute of Child Health (UK)

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