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Study Towards the Effects of Post-discharge nutrition on growth and body composition of infants born less than or equal to 32 weeks gestation and/or less than or equal to 1500 g birth weight

Submission date 04/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/08/2005	**Overall study status** Completed	
Last Edited 08/04/2015	**Condition category** Neonatal Diseases	

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
NTR55

Study information

Scientific Title
Study Towards the Effects of Post-discharge nutrition on growth and body composition of infants born less than or equal to 32 weeks gestation and/or less than or equal to 1500 g birth weight

Acronym
STEP

Study objectives
1. To study the effects of post-dicharge nutrition on the growth, body composition, metabolism and neurodevelopment of premature infants
2. To study the effects of catch-up growth on the body composition, metabolism and neurodevelopment of premature infants

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local ethics committee

Study design
Randomised single-blind active-controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Prematurity, growth retardation (intrauterine and/or postnatal)

Interventions
Randomisation to post-discharge or term formula between 0 and 6 months corrected age. Breast milk group as a control group. All the formula and the breast milk with fortifier are prescribed in a volume of 175 ± 15 ml/kg/day (160 - 190 ml/kg/day).

The infants are seen at the outpatient clinic at 0, 3, 6, 12 and 24 months corrected age. Anthropometry is performed and motorneurodevelopment is tested by a physiotherapist. At 0, 3 and 6 months corrected age a fasting venous blood sample is taken and urine is collected. At 0 and 6 months corrected age the body composition is established with a dual-energy x-ray absorptiometry (DEXA) scan. Parents keep weekly dairies and telephonic support is offered on a regular basis.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Growth and body composition (bone density, fat percentage).

Secondary outcome measures
1. Anaemia
2. Bone markers
3. Protein status
4. Metabolism (oleic acid [OA] glucose, cholesterol, insulin-like growth factor-I [IGF-I])
5. Free fatty acids in red blood cells
6. Neurodevelopment

Overall study start date
01/08/2003

Completion date
01/09/2009

Eligibility

Key inclusion criteria
1. Gestational age less than or equal to 32 weeks with a birth weight less than or equal to 2000 g or a birth weight less than or equal to 1500 g and a gestational age less than or equal to 34 weeks
2. At least one parent or caretaker who speaks Dutch or English

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
150

Key exclusion criteria
Conditions that influence the growth like:
1. Severe congenital anomalies
2. Bronchopulmonary dysplasia defined as an O2 requirement above 25% at 36 weeks gestation, any O2 requirement at 38 weeks gestation or any respiratory support at 40 weeks gestation
3. Severe intracerebral haemorrhage or ischaemia diagnosed before inclusion
4. Gastrointestinal surgery and gastrointestinal diseases known to influence growth

Date of first enrolment
01/08/2003

Date of final enrolment
01/09/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
P.O. Box 7057, dep 9D11
Amsterdam
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Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (The Netherlands)

Sponsor details
Department of Paediatrics and Neonatology
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1007 MB

Sponsor type
University/education

Website
http://www.vumc.nl

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Industry

Funder Name
Friesland Foods (The Netherlands) - Department of Research and Development

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2011		Yes	No
Results article	results	01/09/2012		Yes	No
Results article	results	01/08/2014		Yes	No