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Effects of feeding during the first months of life in post-natal health in babies born small for gestational age (SGA)

Submission date	Recruitment status	[ ] Prospectively registered
08/12/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/12/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/12/2008	Pregnancy and Childbirth	[ ] 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
N/A

Study information

Scientific Title

Influence of early feeding in subsequent cardiovascular risks in infants born small for gestational age: a randomised controlled trial

Acronym
PSO

Study objectives
1. Breastfed small for gestational age (SGA) babies will gain more lean mass and less fat mass over the first 4 months of life
2. SGA babies will have more vsiceral fat at age 24 months as compared to babies born appropriate for gestational age (AGA)
3. SGA babies fed enriched formula will be more insulin resistant, have higher levels of insulin-like growth factor 1 (IGF-1) and altered levels of adipokines, as compared to breastfed SGA babies and SGA babies fed with regular formula

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee of Hospital Sant Joan de Déu, Esplugues have given approval on the 15th May 2008

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Small for gestational age (SGA), adipokines, cardiovascular risk factors

Interventions
Newborns born SGA who will not be breastfed will be randomised to receive a regular or an enriched formula for 4 months. Assessments at birth, 15 days, 4, 12 and 24 months (sampling, dual energy X-ray absorptiometry [DXA] and ultrasound).

Regular formula: Fat: 28.9 g%; carhohydrates: 55.0 g%; proteins: 11.7 g%
Enriched formula: Fat: 24.7 g%; carbohydrates: 54.9 g%; proteins: 14.5 g%
Feeding is ad libitum and following the recommendations of the primary care paediatricians. This is usually every 3 hours the first month, and every 4 hours thereafter. No additional food is allowed until after month 4.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Body composition at age 15 days and at age 4, 12 and 24 months (DXA).

Key secondary outcome(s))
1. Insulin
2. IGF-1
3. Adipokines
4. Visceral fat

Measured in cord blood, and in fasting samples at age 4, 12 and 24 months.

Completion date
10/08/2010

Eligibility

Key inclusion criteria
1. Maternally uncomplicated pregnancy (no gestational diabetes, no pre-eclampsia, no use of alcohol, drugs or illicit substances), with delivery at Hospital Sant Joan de Déu in Barcelona
2. Birthweight AGA (between -1 and +1 SD) or SGA (between 1.8 kg and -2 SD) after a term gestation (37 - 42 weeks)
3. Availability of cord serum
4. Ethnically Catalan background

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Dysmorphic features
2. 10-minute Apgar score below 7

Date of first enrolment
10/06/2008

Date of final enrolment
10/08/2010

Locations

Countries of recruitment
Spain

Study participating centre
Endocrinology Unit
ESplugues
Spain
08950

Sponsor information

Organisation
Hospital Sant Joan de Deu (Spain)

ROR
https://ror.org/001jx2139

Funder(s)

Funder type
Research organisation

Funder Name
The Carlos III Health Institute (Instituto de Salud Carlos III) (Spain) (ref: PI080443)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration