

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

Submission date 08/12/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/12/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/12/2008	Condition category Pregnancy and Childbirth	<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
Prof Lourdes Ibanez

Contact details
Endocrinology Unit
Hospital Sant Joan de Deu
ESplugues
Spain
08950
+34 93 28 04 000
libanez@hsjdbcn.org

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 visceral 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%; carbohydrates: 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes