

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

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

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Quality of life

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure**

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

## **Secondary outcome measures**

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.

## **Overall study start date**

10/06/2008

## **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

## **Age group**

Neonate

## **Sex**

Both

**Target number of participants**

90 (SGA), 50 (AGA)

**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)

**Sponsor details**

Passeig de Sant Joan de Deu 2

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Spain

08950

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libanez@hsjdbcn.org

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.hsjdbcn.org/index.jsp>

**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**

### **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