# Use of insulin sensitisers to revert metabolic syndrome

Submission date	Recruitment status	[X] Prospectively registered
20/02/2009	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
27/02/2009	Completed	Results
Last Edited	Condition category	Individual participant data
27/02/2009	Pregnancy and Childbirth	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 Déu University of Barcelona Esplugues Barcelona Spain 08950

# Additional identifiers

Protocol serial number EC08/00160

# Study information

### Scientific Title

Endocrine-metabolic and body composition effects of metformin administration in prepubertal children with a low birthweight for gestational age, postnatal catch-up growth, and risk markers for metabolic syndrome: a double-blind randomised placebo-controlled trial

### **Acronym**

SGA-Met10

### **Study objectives**

Administration of metformin for two years in prepubertal children with a history of low birthweight, postnatal catchup and metabolic syndrome will improve insulin sensitivity, and reduce visceral fat and intrahepatic lipid content.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Hospital Sant Joan de Deu, approved on 08/09/2008 (ref: Act. 98)

### Study design

Double-blind randomised placebo-controlled trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Low birthweight, subsequent catchup and metabolic syndrome

#### **Interventions**

Participants will be randomly allocated (randomisation ratio 1:1) to receive metformin (oral; 425 mg/day) or placebo over 2 years.

### Intervention Type

Other

#### Phase

Not Applicable

### Primary outcome(s)

- 1. Insulin sensitivity (homeostasis model assessment)
- 2. Fasting insulin
- 3. IGF-I
- 4. Visceral fat

All primary and secondary outcomes will be assessed at 0, 6, 12 and 24 months on metformin, and at 6 months off metformin.

# Key secondary outcome(s))

- 1. Puberty start (girls)
- 2. Carotid intima-media thickness

All primary and secondary outcomes will be assessed at 0, 6, 12 and 24 months on metformin, and at 6 months off metformin.

### Completion date

15/04/2011

# **Eligibility**

### Key inclusion criteria

- 1. Prepubertal children, both males and females
- 2. Birthweight less or equal to -2.0 SDS for gestational age, at term (37-42 week)
- 3. Postnatal catchup (weight and height >p25 in the first 2 years of life)
- 4. Body Mass Index (BMI) >p75 and <p97
- 5. Increased visceral fat (MR): >p75
- 6. Insulin-like growth factor-I (IGF-I) levels >p75
- 7. Fasting insulin >p75

### Participant type(s)

Patient

## Healthy volunteers allowed

No

### Age group

Child

#### Sex

Αll

### Key exclusion criteria

- 1. Syndromatic, chromosomal, or infectious origin of Small for Gestational Age (SGA)
- 2. Gestational diabetes
- 3. Hypothyroidism
- 4. Systemic disease
- 5. Precocious pubarche
- 6. Precocious puberty

### Date of first enrolment

15/04/2009

### Date of final enrolment

15/04/2011

# **Locations**

### Countries of recruitment

Spain

Study participating centre Endocrinology Unit Barcelona 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: EC08/00160)

# **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 11/11/2025 No Yes