

# Addition of metformin to growth hormone for short children born small for gestational age

<b>Submission date</b> 12/02/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 27/05/2010	<b>Condition category</b> Pregnancy and Childbirth	<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

Dr Paula Casano

### Contact details

Hospital Sant Joan de Deu  
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Spain  
08950

## Additional identifiers

### EudraCT/CTIS number

2009-016246-12

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers

2009-016246-12

# Study information

## Scientific Title

Effects of metformin on cardiovascular risk factors in prepubertal children born small for gestational age without postnatal catch-up growth, currently treated with growth hormone: a prospective randomised clinical trial

## Acronym

GH-MET

## Study objectives

In prepubertal small for gestational age (SGA) children treated with growth hormone (GH), the addition of metformin will have beneficial effects on cardiovascular risk markers and body composition.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethical Committee of Hospital Sant Joan de Deu, University of Barcelona, approved on the 2nd February 2010

## Study design

Prospective randomised double-blind two-armed clinical trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## 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

Short children born small for gestational age

## Interventions

Administration of metformin (425 mg/d) or placebo per oral once daily (at night) over 12 months. Total duration of follow-up is 18 months.

## Intervention Type

Drug

**Phase**

Phase II

**Drug/device/biological/vaccine name(s)**

Metformin

**Primary outcome measure**

Insulin sensitivity (homeostatic model assessment [HOMA]), fasting insulin and visceral fat. An increase in insulin sensitivity (estimated using the HOMA method) equal or greater than 30%, accompanied by a decrease of 10% in visceral fat mass, will be considered a positive and discriminative response.

Measured at baseline, 9 months and 18 months.

**Secondary outcome measures**

1. Pubertal onset (girls)
2. Insulin-like growth factor-1 (IGF-1)
3. Intima-media thickness (IMT)
4. Lipid profile (triglycerides)
5. Adipokines

Measured at baseline, 9 months and 18 months.

**Overall study start date**

01/04/2010

**Completion date**

01/10/2011

## **Eligibility**

**Key inclusion criteria**

1. Prepubertal boys and girls between 7- 10 years old
2. SGA: weight less than or equal to -2 SD for gestational age and gender
3. Full-term pregnancy (gestational age between 37 - 42 weeks)
4. Caucasian origin
5. Prepubertal (Tanner I)
6. GH treatment during the previous 1 - 3 years and currently on treatment at the time of the study
7. Positive response to GH treatment with a 1 SD increase in height velocity

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

7 Years

**Upper age limit**

10 Years

**Sex**

Both

**Target number of participants**

64

**Key exclusion criteria**

1. Known causes of SGA: congenital infections, genetic syndromes
2. Drug and/or alcohol consumption
3. During the study: liver or kidney disorders or oncological disease
4. Thyroid hormone disorders
5. Obesity (body mass index [BMI] greater than or equal to + 2SD for age), glucose intolerance or type 2 diabetes
6. Treatment with glucocorticoids, sex hormones or drugs that could affect glucose tolerance
7. Infectious or inflammatory symptoms in the 15 days prior to sample collection

**Date of first enrolment**

01/04/2010

**Date of final enrolment**

01/10/2011

**Locations****Countries of recruitment**

Spain

**Study participating centre**

Hospital Sant Joan de Deu

Barcelona

Spain

08950

**Sponsor information****Organisation**

Hospital Sant Joan de Deu (Spain)

**Sponsor details**

c/o Paula Casano Sancho

University of Barcelona

Esplugues

Barcelona  
Spain  
08950

**Sponsor type**

Hospital/treatment centre

**Website**

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

**ROR**

<https://ror.org/001jx2139>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Carlos III Institute of Health (Instituto de Salud Carlos III) (Spain) (ref: TRA-131)

## **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