

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

Submission date 12/02/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/05/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/05/2010	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

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Additional identifiers

Clinical Trials Information System (CTIS)
2009-016246-12

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

7 years

Upper age limit

10 years

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration