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

Submission date	Recruitment status	[ ] Prospectively registered
12/02/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/05/2010	Pregnancy and Childbirth	[ ] 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

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