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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

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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
All

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