

Use of insulin sensitisers to revert metabolic syndrome

Submission date 20/02/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/02/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 27/02/2009	Condition category 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

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 measure

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.

Secondary outcome measures

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.

Overall study start date

15/04/2009

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

Age group

Child

Sex

Both

Target number of participants

52

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)

Sponsor details

c/o Prof Lourdes Ibanez

Endocrinology Unit

University of Barcelona

Esplugues

Barcelona

Spain

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Sponsor type

Hospital/treatment centre

Website

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

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

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