

Use of insulin sensitisers to revert metabolic syndrome

Submission date 20/02/2009	Recruitment status No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 27/02/2009	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 27/02/2009	Condition category Pregnancy and Childbirth	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Lourdes Ibanez

Contact details

Endocrinology Unit
Hospital Sant Joan de Déu
University of Barcelona
Esplugues
Barcelona
Spain
08950

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)

Primary study design

Interventional

Study design

Double-blind randomised placebo-controlled trial

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