

Insulin sensitisation to delay pubertal progression in girls: a pilot study in small-for-gestational-age (SGA) girls with an early-normal onset of puberty

Submission date
24/08/2005

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
05/10/2005

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
11/09/2009

Condition category
Urological and Genital Diseases

Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Lourdes Ibañez

Contact details

Hospital Sant Joan de Déu
University of Barcelona
Esplugues
Spain
08950

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Acronym

Metformin-Puberty

Study objectives

Modulation of insulin-signalling contributes to variation in the tempo of pubertal progression in girls.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Advanced and progressive puberty in low-birthweight girls, resulting in final height below target

Interventions

Insulin sensitisation: metformin 850 mg/day versus placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Metformin

Primary outcome(s)

1. Menarche
2. Final height

Key secondary outcome(s)

1. Fasting insulin
2. IGF-I

Completion date

25/06/2006

Eligibility

Key inclusion criteria

1. Birthweight for gestational age below -1.5 standard deviation (SD)
2. Onset of breast development (Tanner stage 2, B2) between age 8-9 years and <12 months before study start
3. Height SD score (SDS) at enrollment at least 1 SD above mid-parental height
4. Height velocity >6 cm/year
5. Progressive puberty, as assessed by pelvic ultrasonography and by gonadotropin and steroid responses to gonadotropin releasing hormone (GnRH) agonist stimulation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

Female

Key exclusion criteria

A family or personal history of diabetes mellitus; a history of precocious pubarche; evidence for thyroid dysfunction, Cushing syndrome, hyperprolactinemia or glucose intolerance; medication known to affect gonadal function or carbohydrate metabolism.

Date of first enrolment

20/10/2002

Date of final enrolment

25/06/2006

Locations

Countries of recruitment

Spain

Study participating centre

Hospital Sant Joan de Déu

Esplugues

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

Hospital Sant Joan de Déu (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2006		Yes	No
Results article	results	01/09/2007		Yes	No