ISRCTN06805028 https://doi.org/10.1186/ISRCTN06805028

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

Registration date
05/10/2005

Overall study status
Completed

Last Edited
11/09/2009

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
1. Menarche
2. Final height

Secondary outcome measures
1. Fasting insulin
2. IGF-I

Overall study start date
20/10/2002

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

Age group
Child

Sex
Female

Target number of participants
22

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)

Sponsor details
University of Barcelona
Passeig de Sant Joan de Déu, 2
Esplugues
Spain
08950

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/001jx2139

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital Sant Joan de Déu (Spain)

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

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