

# 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

## 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?
<a href="#">Results article</a>	results	01/06/2006		Yes	No
<a href="#">Results article</a>	results	01/09/2007		Yes	No