

# Prepubertal insulin sensitisation in girls with a combined history of low birthweight and precocious pubarche

**Submission date**  
11/08/2005

**Recruitment status**  
No longer recruiting

Prospectively registered

Protocol

**Registration date**  
05/10/2005

**Overall study status**  
Completed

Statistical analysis plan

Results

**Last Edited**  
11/07/2008

**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 Ibanez

### Contact details

Hospital Sant Joan de Deu  
University of Barcelona  
Esplugues, Barcelona  
Spain  
08950

## Additional identifiers

## Study information

Scientific Title

### Acronym

P&M

### Study objectives

Insulin sensitisation delays pubertal onset in low birthweight girls with precocious pubarche.

Please note that as of 11/07/2008, this trial has been updated. All updates can be found in the relevant field under the update date.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Added 11/07/2008:

Ethics approval received from the Comité de Recerca, Hospital Sant Joan de Déu, University of Barcelona (Spain) on the 11th April 2001. The original protocol was also approved by the Agencia Española del Medicamento (ref: 01-0056, code HSJD-LIT-01). An amendment was presented in January 2008; the absence of reply from the administration implies approval.

### **Primary study design**

Interventional

### **Study design**

Randomised controlled trial

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Precocious pubarche

### **Interventions**

Randomised subgroups:

1. Metformin 425 mg/day
2. Untreated

Added as of 11/07/2008:

Cross-over of therapy from year 6 of follow-up. All patients have been off therapy from year 5 (July 2007) to year 6.

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Metformin

### **Primary outcome(s)**

Onset of puberty, measured at baseline and every 6 months (timepoints added 11/07/2008)

### **Key secondary outcome(s)**

1. Menarche, measured baseline and every 6 months. All untreated girls are already menarcheal, 14 of 19 treated girls are menarcheal.
2. Final height, measured end of the 6th year

Timepoints added 11/07/2008

**Completion date**

10/10/2007

## Eligibility

**Key inclusion criteria**

Girls with a combined history of low birthweight (less than 1.5 standard deviation score [SDS]) and precocious pubarche (appearance of pubic hair before age 8)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Sex**

Female

**Key exclusion criteria**

1. Congenital adrenal hyperplasia
2. Diabetes mellitus
3. Thyroid dysfunction

**Date of first enrolment**

10/10/2002

**Date of final enrolment**

10/10/2007

## Locations

**Countries of recruitment**

Spain

**Study participating centre**

Hospital Sant Joan de Deu

Esplugues, Barcelona

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	01/09/2004		Yes	No