

# 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# 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.

## 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

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 measure**

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

**Secondary outcome measures**

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

Timepoints added 11/07/2008

**Overall study start date**

10/10/2002

**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

**Age group**

Child

**Sex**

Female

**Target number of participants**

38

**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)

**Sponsor details**

University of Barcelona

Passeig de Sant Joan de Deu, 2

Esplugues, Barcelona

Spain

08950

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.hsjd.org>

**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?
<a href="#">Results article</a>	Results	01/09/2004		Yes	No