

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	<input type="checkbox"/> Prospectively registered
Registration date 05/10/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/07/2008	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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.

Study design

Randomised controlled trial

Primary study design

Interventional

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?
Results article	Results	01/09/2004		Yes	No