ISRCTN08608368 https://doi.org/10.1186/ISRCTN08608368

Insulin sensitisation in post-menarcheal girls with a history of low birthweight and precocious pubarche: effects of the addition of antiandrogen treatment and of the androgen receptor length on body composition and endocrine-metabolic parameters

Submission date	Recruitment status	[_] Prospectively registered
07/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/10/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/09/2009	Urological and Genital Diseases	

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 Deu
Passeig de Sant Joan de Deu 2
Esplugues, Barcelona
Spain
08950

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
The endocrine-metabolic effects of insulin sensitisation +/- antiandrogen therapy will be directly related to the length of CAG repeats of the androgen receptor gene.

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
Ovarian hyperandrogenism

Interventions
Insulin sensitisation +/- antiandrogen treatment

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Insulin, antiandrogen

Primary outcome measure
1. Development of clinical hyperandrogenism
2. Body composition

Secondary outcome measures
1. Decrease of androgens
2. Improvement of insulin sensitivity

Overall study start date
20/10/2003

Completion date
20/10/2006

Eligibility

Key inclusion criteria
1. Post-menarcheal state
2. A history of low birthweight and precocious pubarche
3. Subclinical ovarian hyperandrogenism
4. Hyperinsulinemia

Participant type(s)
Patient

Age group
Child

Sex
Female

Target number of participants
20

Key exclusion criteria
1. Clinical signs of androgen excess
2. Family or personal history of diabetes mellitus
3. Late-onset congenital adrenal hyperplasia

Date of first enrolment
20/10/2003

Date of final enrolment
20/10/2006

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
Passeig de Sant Joan de Deu, 2
Esplugues, Barcelona
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 Deu (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	01/11/2007		Yes	No