

Effects of the addition of low-dose pioglitazone to combined flutamide-metformin treatment on endocrine-metabolic and body composition indices in young women with ovarian hyperandrogenism, hyperinsulinism and cardiovascular risk

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
17/11/2005	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
09/01/2006	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
08/04/2021	Urological and Genital Diseases	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

HSJD-LIT-05

Study information

Scientific Title

Effects of the addition of low-dose pioglitazone to combined flutamide-metformin treatment on endocrine-metabolic and body composition indices in young women with ovarian hyperandrogenism, hyperinsulinism and cardiovascular risk

Study objectives

Hypothesis for the protocol extension added as of 05/07/2007:

Therapy for three years with pioglitazone, metformin and flutamide will reverse the endocrine-metabolic and body composition abnormalities in young women with androgen excess.

Previous hypothesis:

The addition of low-dose pioglitazone to combined flutamide-metformin therapy will result in significant improvements in the endocrine-metabolic and body composition abnormalities associated with hyperandrogenic hyperinsulinism in young women with increased cardiovascular risk.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval was received on the 5th November 2005; extensions approved on the 27th October 2006.

Study design

Double-blind, prospective, randomised, trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Ovarian hyperandrogenism with hyperinsulinism, dyslipemia and cardiovascular risk

Interventions

Please note that, as of 5 July 2007, the anticipated end date of this trial has been extended from 18 July 2006 to 31 December 2008.

Interventions for the protocol extension added as of 05/07/2007:

Over the last 18 months, patients will be randomised to receive for six months:

1. Pioglitazone, metformin and flutamide
2. Pioglitazone, metformin and placebo
3. Placebo, metformin and flutamide, or
4. Placebo, metformin and placebo

The next six months, all patients will be treated with pioglitazone, metformin and flutamide (open phase), and over the last six months of the trial (double blinded, randomised), half of the patients will receive three placebos and the other half will remain on the same treatment.

Previous interventions:

One group will receive pioglitazone, flutamide and metformin; the other group will receive placebo, flutamide and metformin.

Assessment of endocrine-metabolic variables, neutrophil count, C-Reactive Protein (CRP) levels, body composition, carotid intima media thickness at baseline, and at three and six months.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Pioglitazone, flutamide, metformin

Primary outcome(s)

1. C-reactive protein (CRP) levels
2. Neutrophil count
3. Serum androgens
4. Fasting insulin
5. Lipid profile

Key secondary outcome(s)

1. Carotid intima-media thickness
2. Body composition (visceral fat)
3. High molecular weight adiponectin (added as of 05/07/2007 as part of the extension)

Completion date

31/12/2008

Eligibility

Key inclusion criteria

1. Age 18 years or more
2. Menarche at least three years before inclusion
3. Clinical and/or biochemical signs of androgen excess
4. Hyperinsulinism
5. Dyslipidemia
6. Relative hyperneutrophilia, increased C-reactive protein (CRP)
7. Normal liver and kidney functions
8. Absence of non-classical adrenal hyperplasia due to 21-OH (21-hydroxylase) deficiency

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Total final enrolment

38

Key exclusion criteria

1. Age less than 18 years
2. Pregnancy
3. Hyperprolactinemia
4. Cushing's syndrome
5. Abnormal thyroid function
6. Liver or kidney dysfunction
7. Glucose intolerance
8. Type 1 or type 2 diabetes
9. Cutaneous allergy
10. Concomitant therapy with agents influencing lipid or carbohydrate metabolism.
11. Alcoholism
12. Bacterial infections

Date of first enrolment

18/11/2005

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

Spain

Study participating centre

Hospital Sant Joan de Deu
Esplugues
Spain
08950

Sponsor information

Organisation

Hospital Sant Joan de Deu, University of Barcelona (Spain)

ROR

<https://ror.org/001jx2139>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospital Sant Joan de Deu (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		01/09/2009	08/04/2021	Yes	No