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# 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 | [_] Prospectively registered |
|---|---|---|
| 17/11/2005 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 09/01/2006 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] 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

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## Additional identifiers

**EudraCT/CTIS number**

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

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

## Secondary outcome measures
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)

## Overall study start date
18/11/2005

## 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Female

### Target number of participants
40

### 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)

**Sponsor details**
Passeig de Sant Joan de Deu, 2
Esplugues
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 | | 01/09/2009 | 08/04/2021 | Yes | No |