ISRCTN12871246 https://doi.org/10.1186/ISRCTN12871246

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

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.

Primary study design
Interventional

Study design
Double-blind, prospective, randomised, trial

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