# Clinical trial results:
# The effect of antidepressant therapy on quality of life, physical and menthal health and cortisole metabolism in PCOS.

## Summary

| | |
|---|---|
| EudraCT number | 2010-022319-20 |
| Trial protocol | DK |
| Global end of trial date | 30 June 2015 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 30 November 2020 |
| First version publication date | 30 November 2020 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | 24638418 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | - |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Odense University Hospital |
| Sponsor organisation address | kløvervænget 6, Odense, Denmark, 5000 |
| Public contact | Department of Endocrinology, Odense University Hospital, department of Endocrinology, +45 65412502, |
| Scientific contact | Marianne Andersen, Odense University Hospital, department of Endocrinology, +45 65412502, msa@rsyd.dk |

Notes:

**Paediatric regulatory details**

| | |
|---|---|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 29 October 2020 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 30 June 2015 |
| Global end of trial reached? | Yes |
| Global end of trial date | 30 June 2015 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

1)To investigate if treatment with cipralex will diminish the adrenal activity in PCOS patients versus placebo.
2)To investigate if quality of life, physical and menthal health improves, in PCOS patient on cipralex treatment versus placebo.

Protection of trial subjects:

National authorities in Denmark

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 01 September 2011 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Denmark: 42 |
| Worldwide total number of subjects | 42 |
| EEA total number of subjects | 42 |

Notes:

### Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 42 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

42 overweight premenopausal women with PCOS and no clinical depression

### Pre-assignment

Screening details:

Invited from PCOS clinic

### Period 1

| | |
|---|---|
| Period 1 title | overall trial (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Data analyst |

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Placebo |

Arm description: -

| | |
|---|---|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

1 tablet/day

| | |
|---|---|
| **Arm title** | SSRI |

Arm description:

escitalopram

| | |
|---|---|
| Arm type | Active comparator |
| Investigational medicinal product name | escitalopram |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

escitalopram 20 mg/day

| **Number of subjects in period 1** | Placebo | SSRI |
|---|---|---|
| Started | 21 | 21 |
| Completed | 19 | 20 |
| Not completed | 2 | 1 |
| Consent withdrawn by subject | 2 | - |
| Adverse event, non-fatal | - | 1 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Placebo |
| Reporting group description: - | |
| Reporting group title | SSRI |
| Reporting group description: escitalopram | |

| Reporting group values | Placebo | SSRI | Total |
|---|---|---|---|
| Number of subjects | 21 | 21 | 42 |
| Age categorical<br>Units: Subjects | | | |
| In utero | | | 0 |
| Preterm newborn infants (gestational age < 37 wks) | | | 0 |
| Newborns (0-27 days) | | | 0 |
| Infants and toddlers (28 days-23 months) | | | 0 |
| Children (2-11 years) | | | 0 |
| Adolescents (12-17 years) | | | 0 |
| Adults (18-64 years) | | | 0 |
| From 65-84 years | | | 0 |
| 85 years and over | | | 0 |
| Age continuous | | | |
| age | | | |
| Units: years | | | |
| geometric mean | 31 | 33 | |
| standard deviation | ± 6 | ± 7 | - |
| Gender categorical<br>Units: Subjects | | | |
| Female | 21 | 21 | 42 |
| Male | 0 | 0 | 0 |

## End points

| End points reporting groups | |
|---|---|
| Reporting group title | Placebo |
| Reporting group description: - | |
| Reporting group title | SSRI |
| Reporting group description:<br>escitalopram | |

| Primary: BMI | |
|---|---|
| End point title | BMI |
| End point description: | |
| End point type | Primary |
| End point timeframe:<br>12 weeks | |

| End point values | Placebo | SSRI | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 20 | | |
| Units: kg/m2 | | | | |
| geometric mean (standard deviation) | 35.7 (± 6.1) | 35.9 (± 6.6) | | |

### Statistical analyses

| Statistical analysis title | Statistical analysis |
|---|---|
| Comparison groups | Placebo v SSRI |
| Number of subjects included in analysis | 39 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.05 |
| Method | Wilcoxon (Mann-Whitney) |

## Adverse events

| Adverse events information | |
|---|---|
| Timeframe for reporting adverse events: 3 months | |
| Assessment type | Systematic |
| **Dictionary used** | |
| Dictionary name | MedDRA |
| Dictionary version | 1 |
| **Reporting groups** | |
| Reporting group title | placebo |
| Reporting group description: - | |
| Reporting group title | SSRÍ |
| Reporting group description: - | |

| Serious adverse events | placebo | SSRÍ | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | placebo | SSRÍ | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 21 (4.76%) | |
| Gastrointestinal disorders | | | |
| nausea | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 21 (4.76%) | |
| occurrences (all) | 0 | 1 | |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported

### Online references

http://www.ncbi.nlm.nih.gov/pubmed/29472241