



## Clinical trial results:

### The effect of antidepressant therapy on quality of life, physical and mental health and cortisol 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 | klørvænget 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:

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**Results analysis stage**

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|  |                 |
|--|-----------------|
| 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:

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**General information about the trial**

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Main objective of the trial:

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

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**Population of trial subjects**

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**Subjects enrolled per country**

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

Notes:

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**Subjects enrolled per age group**

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|   |    |
|---|----|
| 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 |
|------------------------------|-----|

|                  |         |
|------------------|---------|
| <b>Arm title</b> | 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

|                  |      |
|------------------|------|
| <b>Arm title</b> | 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:<br>escitalopram |         |

| Reporting group values                                | Placebo | SSRI | Total |
|---|---------|------|-------|
| Number of subjects                                    | 21      | 21   | 42    |
| Age categorical                                       |         |      |       |
| Units: Subjects                                       |         |      |       |
| In utero  |         |      | 0     |
| Preterm newborn infants<br>(gestational age < 37 wks) |         |      | 0     |
| Newborns (0-27 days)                                  |         |      | 0     |
| Infants and toddlers (28 days-23<br>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                                    |         |      |       |
| 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

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported

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### Online references

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