



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
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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:

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 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:

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
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Arm title	Placebo
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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
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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			
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			
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:	escitalopram

Primary: BMI

End point title	BMI
End point description:	
End point type	Primary
End point timeframe:	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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	1
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Reporting groups

Reporting group title	placebo
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Reporting group description: -

Reporting group title	SSRÍ
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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>