Clinical trial results:
Neural, Genetic, and Peripheral Correlates of SSRI Pharmaco-Response

Summary

EudraCT number	2010-023446-70
Trial protocol	AT
Global end of trial date	01 April 2015

Results information

Result version number	v1 (current)
This version publication date	07 May 2022
First version publication date	07 May 2022

Trial information

Trial identification

Sponsor protocol code	NCT01251471

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01251471
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Austrian Science Fund (FWF)
Sponsor organisation address	Sensengasse 1, Vienna, Austria, 1090
Public contact	Assoc.Prof. Priv.Doz. Dr. Lukas Pezawas, Medical University of Vienna, lukas.pezawas@meduniwien.ac.at
Scientific contact	Assoc.Prof. Priv.Doz. Dr. Lukas Pezawas, Medical University of Vienna, lukas.pezawas@meduniwien.ac.at

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	01 April 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 April 2015
Global end of trial reached?	Yes
Global end of trial date	01 April 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to relate functional and structural MR parameters (e.g. local and system level BOLD signal, gray matter, structural connectivity, surface and parcellation measures) to drug response and remission.

Protection of trial subjects:

1. Escitalopram is available in clinical routine and drug treatment within this study did not differ from clinical routine including safety measure
2. With regard to magnetic resonance imaging safety measures such as ear protection was provided.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 September 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 22
Worldwide total number of subjects	22
EEA total number of subjects	22

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)	22
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited at the outpatient clinic of the Department of Psychiatry and Psychotherapy at the Medical University of Vienna or by online and bulletin board advertisements.

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	22
Number of subjects completed	22

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Patient arm

Arm description:

1) MDD diagnosis according to DSM-IV (German Structured Clinical Interview, SCID-I) and absence of any other axis I disorder, (2) Montgomery-Åsberg Depression Rating Scale (MADRS) score ≥20 and ≤30, (3) age between 18 and 50 years, (4) right-handedness, and (5) willingness to provide informed consent and ability to be managed as outpatient.

Arm type	treatment arm
Investigational medicinal product name	Escitalopram
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Escitalopram dosing reflected clinical practice with a fixed dose of 10 mg and the option to increase to 20 mg after d28 until the end of study visit in case of nonresponse.

Number of subjects in period 1	Patient arm
Started	22
Completed	22

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	22	22	
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 Units: years			
arithmetic mean	31.5		
standard deviation	± 7.7	-	
Gender categorical Units: Subjects			
Female	11	11	
Male	11	11	

End points

End points reporting groups

Reporting group title	Patient arm

Reporting group description:

1) MDD diagnosis according to DSM-IV (German Structured Clinical Interview, SCID-I) and absence of any other axis I disorder, (2) Montgomery-Åsberg Depression Rating Scale (MADRS) score ≥20 and ≤30, (3) age between 18 and 50 years, (4) right-handedness, and (5) willingness to provide informed consent and ability to be managed as outpatient.

Primary: Primary Measure

End point title	Primary Measure[1]

End point description:

The primary measure of drug response was defined as percent change between pretreatment (d0) and end-of-treatment (d56) MADRS scores: DR = (1- MADRSd56/MADRSd0)*100.

End point type	Primary

End point timeframe:

8 weeks

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: To detect time-sensitive neural activation that could mediate drug response, the interaction-term of drug response and scan session was calculated. The goal of the study was to determine neural markers of drug response and not the efficacy of escitalopram, which is already been studied in clinical trials.

End point values	Patient arm			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: no unit	22			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: Adverse events were clinically assessed at each visit.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	18.0

Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: There have been non-serious adverse events in this rather small sample

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/30718459