Clinical trial results:
Multimodal Assessment of Neurobiological Markers for Psychiatric Disorders

Summary

EudraCT number	2011-004860-31
Trial protocol	AT
Global end of trial date	01 September 2016

Results information

Result version number	v1 (current)
This version publication date	11 March 2021
First version publication date	11 March 2021

Trial information

Trial identification

Sponsor protocol code	v4_20150205

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01477203
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Waehringerguertel 18-20, Vienna, Austria, 1090
Public contact	Department of Psychiatry, Medical University of Vienna, +43 1404003825, rupert.lanzenberger@meduniwien.ac.at
Scientific contact	Department of Psychiatry, Medical University of Vienna, +43 1404003825, rupert.lanzenberger@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 September 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 September 2016
Global end of trial reached?	Yes
Global end of trial date	01 September 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

MAN-BIOPSY pursues the concrete research question whether novel biological and psycho-physiological clusters or categories can be defined to improve treatment and minimize side effects in psychiatry, based on a synopsis of physiological, behavioural, genetic and endocrinological parameters. One major aspect of our research approach is its focuses on the identification of dysfunctions in fundamental information processing mechanisms and neurocomputational mechanisms, and is not restricted to symptom-oriented tasks.
The main objectives of MAN-BIOPSY are therefore
- to identify biological and psycho-physiological parameters for major depressive disorders and anxiety disorders, and
- to identify predictive markers for treatment response and type/severity of side effects for these disorders.

Protection of trial subjects:

- Patients were observed by medical staff during the entire experimental procedures. - Regular visits were performed in acute patients between scanning sessions and pharmacotherapy
-During MRI measurements respiratory rate was monitored

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 November 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: 158
Worldwide total number of subjects	158
EEA total number of subjects	158

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	158
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment was performed via advertisement on dedicated mesage boards.

Pre-assignment

Screening details:

In total 255 subjects were screened, 158 were included in the study

Period 1

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

Blinding implementation details:

Acute patients received non-blinded psychopharmacological treatment according to international guidelines.

Arms

Are arms mutually exclusive?	Yes
Arm title	Healthy controls

Arm description: -

Arm type	2 MRI Scans, no study medication

No investigational medicinal product assigned in this arm

Arm title	acute major depression

Arm description:

aMD

Arm type	Experimental
Investigational medicinal product name	escitalopram
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

5mg/d increased to 10mg/d within the first week

efficacy was evaluated after 6 weeks: change to second line treatment was performed in case of non-response (Venlafaxin/Mirtazapin)

Arm title	rMDD

Arm description:

remitted MDD

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1[1]	Healthy controls	acute major depression	rMDD
Started	54	44	43
Completed	33	26	36
Not completed	21	18	7
Physician decision	8	4	3
MRI contraindication: metal	-	-	1
fMRI technical problems	9	1	-
manic episode	-	1	-
claustrophobic reaction	1	3	-
MRI structural abnormalities	1	-	1
Lost to follow-up	2	3	2
Protocol deviation	-	6	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: No systematic analyses of outcomes of anxiety patients has been conducted so far. Thus, data from healthy controls, acute MDD and remitted patients are given.

Baseline characteristics

Reporting groups	
Reporting group title	Healthy controls
Reporting group description: -	
Reporting group title	acute major depression
Reporting group description: aMD	
Reporting group title	rMDD
Reporting group description: remitted MDD	

Reporting group values	Healthy controls	acute major depression	rMDD
Number of subjects	54	44	43
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	54	44	43
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	26.6	30.4	28.5
standard deviation	± 6.8	± 9.7	± 8.2
Gender categorical Units: Subjects			
Female	33	32	27
Male	21	12	16

Reporting group values	Total		
Number of subjects	141		
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)	141		
From 65-84 years	0		

85 years and over	0		

Age continuous Units: years arithmetic mean standard deviation	- 		
Gender categorical Units: Subjects			
Female	92		
Male	49		

Subject analysis sets

Subject analysis set title	Healthy controls
Subject analysis set type	Per protocol
Subject analysis set description: Healthy controls that sucessfully ccompleted the protocol, all data available.	
Subject analysis set title	acute major depression
Subject analysis set type	Per protocol
Subject analysis set description: Acute MDD patients that sucessfully ccompleted the protocol, all data available.	
Subject analysis set title	rMDD
Subject analysis set type	Per protocol
Subject analysis set description: Remitted MDD patients that sucessfully ccompleted the protocol, all data available.	

Reporting group values	Healthy controls	acute major depression	rMDD
Number of subjects	33	26	36
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	33	26	36
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	26.6	30.4	28.5
standard deviation	± 6.8	± 9.7	± 8.2
Gender categorical Units: Subjects			
Female	20	19	23
Male	13	7	13

End points

End points reporting groups

Reporting group title	Healthy controls
Reporting group description: -	
Reporting group title	acute major depression
Reporting group description: aMD	
Reporting group title	rMDD
Reporting group description: remitted MDD	
Subject analysis set title	Healthy controls
Subject analysis set type	Per protocol
Subject analysis set description: Healthy controls that sucessfully ccompleted the protocol, all data available.	
Subject analysis set title	acute major depression
Subject analysis set type	Per protocol
Subject analysis set description: Acute MDD patients that sucessfully ccompleted the protocol, all data available.	
Subject analysis set title	rMDD
Subject analysis set type	Per protocol
Subject analysis set description: Remitted MDD patients that sucessfully ccompleted the protocol, all data available.	

Primary: Task related activity

End point title	Task related activity
End point description:	
End point type	Primary
End point timeframe: MRI I - MRI II (~3 months)	

End point values	Healthy controls	acute major depression	rMDD	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	33	26	36	
Units: BOLD signal				
number (not applicable)	33	26	36	

Statistical analyses

Statistical analysis title	Linear regression
Comparison groups	Healthy controls v rMDD

Number of subjects included in analysis	69
Analysis specification	Post-hoc
Analysis type	other
P-value	< 0.05
Method	Regression, Linear

Adverse events

Adverse events information	
Timeframe for reporting adverse events: during entire trial	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	18.0

Reporting groups	
Reporting group title	All participants

Reporting group description: -

Serious adverse events	All participants		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 158 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	All participants		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 158 (0.63%)		
Psychiatric disorders			
Manic episode			
subjects affected / exposed	1 / 158 (0.63%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 February 2015	additional clinical follow-up investigation

Notes:

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/23769917

http://www.ncbi.nlm.nih.gov/pubmed/28108394

http://www.ncbi.nlm.nih.gov/pubmed/25324216

http://www.ncbi.nlm.nih.gov/pubmed/28117844

http://www.ncbi.nlm.nih.gov/pubmed/29422521

http://www.ncbi.nlm.nih.gov/pubmed/25541513

http://www.ncbi.nlm.nih.gov/pubmed/31175273

http://www.ncbi.nlm.nih.gov/pubmed/31175352