



Clinical trial results: Effects of Vortioxetine in Mild Cognitive Impairment measured by Functional Magnetic Resonance Imaging Summary

EudraCT number	2019-001836-69
Trial protocol	AT
Global end of trial date	04 December 2024

Results information

Result version number	v1 (current)
This version publication date	30 January 2026
First version publication date	30 January 2026

Trial information

Trial identification

Sponsor protocol code	Vort-MCI_001
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Waehringer Guertel 18-20, Vienna, Austria, 1090
Public contact	Department of Psychiatry, Medical University of Vienna, +43 14040035470,
Scientific contact	Department of Psychiatry, Medical University of Vienna, +43 14040035470,

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	04 December 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 December 2024
Global end of trial reached?	Yes
Global end of trial date	04 December 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To measure the effect of vortioxetine 10mg or 20mg on brain functional connectivity (FC) assessed by functional magnetic resonance imaging (fMRI) and neuropsychological parameters.

Protection of trial subjects:

Vivienne Matev 13.01.2026 10:59 • Primary Objective: To measure the effect of vortioxetine (10mg or 20mg) versus placebo on brain functional connectivity (FC) assessed by functional magnetic resonance imaging (fMRI). Secondary Objective: To measure the effect of the study drug on neuropsychological parameters.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2021
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: 47
Worldwide total number of subjects	47
EEA total number of subjects	47

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)	5
From 65 to 84 years	42
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Vivienne Matev 13.01.2026 11:01 • Subjects were recruited at the memory clinic of the Department of Psychiatry and Psychotherapy at the Medical University of Vienna, as well as through advertisements in local newspapers.

Pre-assignment

Screening details:

Study subjects were 54 to 80 years of age (mean age 70 ± 6.86 , 31 male, 16 female) and met criteria for MCI following the criteria stipulated by the National Institute on Aging – Alzheimer's Association (NIA-AA) workgroups on diagnostic guidelines for Alzheimer's disease (Albert et al, 2011).

Period 1

Period 1 title	Medication (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:

Tablets will have to be taken orally once a day (q. d.) in the morning for a total duration of 12 weeks.

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:

Tablets will have to be taken orally once a day (q. d.) in the morning for a total duration of 12 weeks.

Arm title	Vortioxetin 10mg
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Arm description:

. Vortioxetine will be started at a daily dose of 5mg for 3 days. Tablets will have to be taken orally once a day (q. d.) in the morning for a total duration of 12 weeks

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

Dosage and administration details:

Vortioxetine will be started at a daily dose of 5mg for 3 days. 10mg tablets will have to be taken orally once a day (q. d.) in the morning for a total duration of 12 weeks.

Arm title	Vortioxetin 20mg
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Arm description:

20 mg tablets of vortioxetine will have to be taken orally once a day (q. d.) in the morning for a total duration of 12 weeks.

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

Dosage and administration details:

Vortioxetine will be started at a daily dose of 5mg for 3 days. Patients in the vortioxetine 20mg group will receive 10mg for further 3 days before dose increase to 20mg. 20mg tablets will have to be taken orally once a day (q. d.) in the morning for a total duration of 12 weeks.

Number of subjects in period 1	Placebo	Vortioxetin 10mg	Vortioxetin 20mg
Started	15	16	16
Completed	15	16	16

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description: Tablets will have to be taken orally once a day (q. d.) in the morning for a total duration of 12 weeks.	
Reporting group title	Vortioxetin 10mg
Reporting group description: . Vortioxetine will be started at a daily dose of 5mg for 3 days. Tablets will have to be taken orally once a day (q. d.) in the morning for a total duration of 12 weeks	
Reporting group title	Vortioxetin 20mg
Reporting group description: 20 mg tablets of vortioxetine will have to be taken orally once a day (q. d.) in the morning for a total duration of 12 weeks.	

Reporting group values	Placebo	Vortioxetin 10mg	Vortioxetin 20mg
Number of subjects	15	16	16
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)	1	3	1
From 65-84 years	14	13	15
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	4	5	7
Male	11	11	9

Reporting group values	Total		
Number of subjects	47		
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)	5		
From 65-84 years	42		
85 years and over	0		

Gender categorical			
Units: Subjects			
Female	16		
Male	31		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Tablets will have to be taken orally once a day (q. d.) in the morning for a total duration of 12 weeks.	
Reporting group title	Vortioxetin 10mg
Reporting group description: . Vortioxetine will be started at a daily dose of 5mg for 3 days. Tablets will have to be taken orally once a day (q. d.) in the morning for a total duration of 12 weeks	
Reporting group title	Vortioxetin 20mg
Reporting group description: 20 mg tablets of vortioxetine will have to be taken orally once a day (q. d.) in the morning for a total duration of 12 weeks.	
Subject analysis set title	Score change from baseline o
Subject analysis set type	Per protocol
Subject analysis set description: Statistical analysis of neuropsychological data was performed using the R Project for Statistical Computing (https://www.r-project.org/). Changes in cognitive performance, measured by total test scores, were analyzed using linear mixed models (LMM), with time as a within-subjects factor and treatment group (vortioxetine 10mg, 20mg, or placebo) as a between-subjects factor, with the significance level set at $\alpha = 0.05$. Post-hoc Tukey tests were computed to account for multiple comparisons.	

Primary: Score change from baseline on the verbal learning test (VLMT)

End point title	Score change from baseline on the verbal learning test (VLMT)
End point description:	
End point type	Primary
End point timeframe: baseline, week 4, week 8, week 12	

End point values	Placebo	Vortioxetin 10mg	Vortioxetin 20mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	15	16	16	
Units: test score				
arithmetic mean (standard deviation)	3.4 ($\pm$ 6.06)	5.31 ($\pm$ 7.12)	5.44 ($\pm$ 6.29)	

Statistical analyses

Statistical analysis title	Score change
Statistical analysis description: Statistical analysis of neuropsychological data was performed using the R Project for Statistical Computing (https://www.r-project.org/). Changes in cognitive performance, measured by total test scores, were analyzed using linear mixed models (LMM), with time as a within-subjects factor and treatment group (vortioxetine 10mg, 20mg, or placebo) as a between-subjects factor, with the significance level set at $\alpha = 0.05$. Post-hoc Tukey tests were computed to account for multiple comparisons.	

Comparison groups	Placebo v Vortioxetin 10mg v Vortioxetin 20mg
Number of subjects included in analysis	47
Analysis specification	Post-hoc
Analysis type	superiority
P-value	≤ 0.05
Method	Mixed models analysis

Adverse events

Adverse events information

Timeframe for reporting adverse events:

at Week 1,2,4,8,12

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.1
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Tablets will have to be taken orally once a day (q. d.) in the morning for a total duration of 12 weeks.

Reporting group title	Vortioxetin 10mg
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Reporting group description:

. Vortioxetine will be started at a daily dose of 5mg for 3 days. Tablets will have to be taken orally once a day (q. d.) in the morning for a total duration of 12 weeks

Reporting group title	Vortioxetin 20mg
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Reporting group description:

20 mg tablets of vortioxetine will have to be taken orally once a day (q. d.) in the morning for a total duration of 12 weeks.

Serious adverse events	Placebo	Vortioxetin 10mg	Vortioxetin 20mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

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

Non-serious adverse events	Placebo	Vortioxetin 10mg	Vortioxetin 20mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	4 / 16 (25.00%)
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	4 / 16 (25.00%)
occurrences (all)	0	1	4

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