



Clinical trial results: Amyloid imaging in late life depression Summary

EudraCT number	2009-018064-95
Trial protocol	BE
Global end of trial date	13 June 2023

Results information

Result version number	v1 (current)
This version publication date	24 January 2026
First version publication date	24 January 2026
Summary attachment (see zip file)	published_data (Takamiya_2021_Scireports.pdf)

Trial information

Trial identification

Sponsor protocol code	S52151
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	KU Leuven
Sponsor organisation address	Oude Markt 13, Leuven, Belgium, 3000
Public contact	Mathieu Vandenbulcke, KU Leuven, 32 16346790, mathieu.vandenbulcke@uzleuven.be
Scientific contact	Mathieu Vandenbulcke, KU Leuven, 32 16346790, mathieu.vandenbulcke@uzleuven.be

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	03 August 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 November 2015
Global end of trial reached?	Yes
Global end of trial date	13 June 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate if late depression is associated with increased cerebral amyloid deposition, we will carry out a voxel-based comparison of the 18F-flutemetamol images between patients with life depression and healthy controls using a two-sample t test in SPM05.

Protection of trial subjects:

The protocol and all relevant documentation were approved by the Independent Ethics Committees at each participating site (University of Leuven and UPC Kortenberg before initiation. Written informed consent was obtained from all enrolled participants prior to any study procedure, including administration of [¹⁸F]flutemetamol. The trial was conducted in accordance with the principles of Good Clinical Practice, the Declaration of Helsinki, and applicable EU and Belgian regulations. Radiation exposure was minimized and monitored, with injection procedures standardized and supervised by qualified nuclear medicine physicians. Adverse events were actively monitored throughout the study and reviewed by the safety monitoring team to ensure participant wellbeing.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 December 2009
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	Belgium: 108
Worldwide total number of subjects	108
EEA total number of subjects	108

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)	10
From 65 to 84 years	92
85 years and over	6

Subject disposition

Recruitment

Recruitment details:

Between 2009-2014, 55 patients >55 yrs with major depressive disorder (DSM-IV) were recruited consecutively from UPC-KU Leuven, Belgium and 53 age- and gender-matched healthy controls were recruited locally via database and newspaper advertisement. 46 controls were from a prior study (PMID:27226443) and stratified by APOE ε4 status.

Pre-assignment

Screening details:

Patients met DSM-IV criteria for major depressive disorder, age >55, without other major psychiatric or neurological illness. Controls had no depression or cognitive impairment, confirmed by clinical and neuropsychological assessment. APOE genotyping and MMSE (>26) were used for subgroup stratification.

Period 1

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

Blinding implementation details:

No blinding was implemented. Group allocation (depressed vs. control) was known during analysis

Arms

Are arms mutually exclusive?	Yes
Arm title	Late life depression

Arm description:

Patients over age 55 with major depressive disorder.

Arm type	Observational patient group
Investigational medicinal product name	NoIMP
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Not assigned
Routes of administration	Not mentioned

Dosage and administration details:

Not applicable – no investigational medicinal product administered. 18F-flutemetamol radiotracer was used only for standard PET imaging procedures

Arm title	Control group
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Arm description:

Age- and gender-matched healthy controls with no history of depression or cognitive impairment.

Arm type	Observational control group
Investigational medicinal product name	NoIMP
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Not assigned
Routes of administration	Not mentioned

Dosage and administration details:

Not applicable – no investigational medicinal product administered. 18F-flutemetamol radiotracer was used only for standard PET imaging procedures

Number of subjects in period 1	Late life depression	Control group
Started	55	53
Completed	48	52
Not completed	7	1
Consent withdrawn by subject	2	-
incomplete PET + MRI dataset	3	-
Vascular lesion	1	-
PET technical failure	1	-
Incomplete PET and MRI data	-	1

Baseline characteristics

Reporting groups

Reporting group title	overall trial
Reporting group description:	
Includes 55 patients and 53 controls that were enrolled in the study prior to exclusion/drop-out	

Reporting group values	overall trial	Total	
Number of subjects	108	108	
Age categorical			
Participants were aged 55 years or older.			
Units: Subjects			
55 years or older	108	108	
Gender categorical			
Gender categorized as Male or Female at baseline			
Units: Subjects			
Female	76	76	
Male	32	32	

Subject analysis sets

Subject analysis set title	Final analysis set
Subject analysis set type	Full analysis

Subject analysis set description:

Includes 48 patients and 52 controls with complete data. Exclusions: 2 patient withdrawals, 1 patient excluded for vascular lesion, 1 patient excluded for PET technical failure, and 4 subjects (3 patients, 1 control) excluded due to missing data.

Reporting group values	Final analysis set		
Number of subjects	100		
Age categorical			
Participants were aged 55 years or older.			
Units: Subjects			
55 years or older	100		
Gender categorical			
Gender categorized as Male or Female at baseline			
Units: Subjects			
Female	70		
Male	30		

End points

End points reporting groups

Reporting group title	Late life depression
Reporting group description: Patients over age 55 with major depressive disorder.	
Reporting group title	Control group
Reporting group description: Age- and gender-matched healthy controls with no history of depression or cognitive impairment.	
Subject analysis set title	Final analysis set
Subject analysis set type	Full analysis
Subject analysis set description: Includes 48 patients and 52 controls with complete data. Exclusions: 2 patient withdrawals, 1 patient excluded for vascular lesion, 1 patient excluded for PET technical failure, and 4 subjects (3 patients, 1 control) excluded due to missing data.	

Primary: Cortical amyloid burden (SUVR PET)

End point title	Cortical amyloid burden (SUVR PET) ^[1]
End point description:	
End point type	Primary
End point timeframe: Baseline (cross-sectional, single assessment)	
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: See attached publication for statistical analyses and results.	

End point values	Late life depression	Control group	Final analysis set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	48	52	100	
Units: Subjects with amyloid PET scan (SUVR)	48	52	100	

Attachments (see zip file)	Full publication – Takamiya et al., Sci Rep
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Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first study assessment to last study assessment per subject

Adverse event reporting additional description:

No serious adverse events were reported during the trial. One non-serious AE occurred, but did not result in study withdrawal. Subject withdrawals occurred for non-AE reasons, including technical issues, no longer wishing to participate, or missing data.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	17
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Reporting groups

Reporting group title	Overall trial
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Reporting group description:

All subjects enrolled in the trial (Late-life depression and Control groups)

Serious adverse events	Overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 100 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0.05 %

Non-serious adverse events	Overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 100 (1.00%)		
Cardiac disorders			
Bradycardia	Additional description: Participant experienced sinus bradycardia with complaints of dizziness, cardiac palpitations and tinnitus. Immediate evaluation by cardiologist. Spontaneously cleared up after 30-60 minutes. Participant continued to participate in the study.		
subjects affected / exposed	1 / 100 (1.00%)		
occurrences (all)	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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Cross-sectional study; some subjects excluded for technical issues or missing data. Imaging outcomes beyond primary objectives were exploratory. Planned longitudinal follow-up to assess conversion to Alzheimer's disease was not performed.

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/35091333>

<http://www.ncbi.nlm.nih.gov/pubmed/27539488>

<http://www.ncbi.nlm.nih.gov/pubmed/28672181>

<http://www.ncbi.nlm.nih.gov/pubmed/34354136>