Clinical trial results:
Rasagiline treatment for Sleep disorders in Parkinson´s disease

Summary

EudraCT number	2010-023756-82
Trial protocol	DE
Global end of trial date	30 April 2015

Results information

Result version number	v1 (current)
This version publication date	03 January 2024
First version publication date	03 January 2024

Trial information

Trial identification

Sponsor protocol code	TUD-RaSPar-051

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01442610
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Technische Universität Dresden
Sponsor organisation address	Helmholtzstraße 10, Dresden, Germany, 01069
Public contact	Koordinierungszentrum für Klinische Studien, Medizinische Fakultät C. G. Carus, kks@ukdd.de
Scientific contact	Koordinierungszentrum für Klinische Studien, Medizinische Fakultät C. G. Carus, kks@ukdd.de

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	31 December 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 April 2015
Global end of trial reached?	Yes
Global end of trial date	30 April 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Reduction of sleep disturbances

Protection of trial subjects:

Patients were closely monitored by the trial group members with regard to safety during the course of the trial. This included a systematically documentation of (S)AEs.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 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	Germany: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	7
From 65 to 84 years	23
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Inclusion of patients with confirmed Parkinson's disease and sleep disturbance according to Pittsburgh Sleep Quality Index (PSQI; > 5 points).

Period 1

Period 1 title	Placebo run-in
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Arm title	All subjects

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

1 tablet; once daily for 2 weeks

Number of subjects in period 1	All subjects
Started	30
Completed	30

Period 2

Period 2 title	Treatment
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes

Arm title	Rasagiline
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Rasagiline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: 1 tablet (1mg Rasagiline), once daily for 8 weeks	

Arm title	Placebo
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: 1 tablet, once daily for 8 weeks	

Number of subjects in period 2	Rasagiline	Placebo
Started	20	10
Completed	20	10

Baseline characteristics

Reporting groups

Reporting group title	All subjects

Reporting group description: -

Reporting group values	All subjects	Total	
Number of subjects	30	30	
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	70		
standard deviation	± 6.9	-	
Gender categorical Units: Subjects			
Female	14	14	
Male	16	16	

Subject analysis sets

Subject analysis set title	Rasagiline: Start of treatment
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects of the Rasagiline group for baseline visit, whose data are presented in the full analysis.

Subject analysis set title	Rasagiline: EoT
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects of the Rasagiline group after 8 weeks of treatment (EoT), whose data are presented in the full analysis.

Subject analysis set title	Placebo: Start of treatment
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects of the Placebo group for baseline visit, whose data are presented in the full analysis.

Subject analysis set title	Placebo: EoT
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects of the Placebo group after 8 weeks of treatment (EoT), whose data are presented in the full analysis.

Reporting group values	Rasagiline: Start of treatment	Rasagiline: EoT	Placebo: Start of treatment
Number of subjects	18	18	7
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
Units: years			
arithmetic mean	69.9	69.9	70.2
standard deviation	± 6.9	± 6.9	± 7.3
Gender categorical			
Units: Subjects			
Female	9	9	3
Male	9	9	4

Reporting group values	Placebo: EoT		
Number of subjects	7		
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
Units: years			
arithmetic mean	70.2		
standard deviation	± 7.3		
Gender categorical			
Units: Subjects			
Female	3		
Male	4		

End points

End points reporting groups

Reporting group title	All subjects
Reporting group description: -	
Reporting group title	Rasagiline
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	
Subject analysis set title	Rasagiline: Start of treatment
Subject analysis set type	Full analysis
Subject analysis set description: Subjects of the Rasagiline group for baseline visit, whose data are presented in the full analysis.	
Subject analysis set title	Rasagiline: EoT
Subject analysis set type	Full analysis
Subject analysis set description: Subjects of the Rasagiline group after 8 weeks of treatment (EoT), whose data are presented in the full analysis.	
Subject analysis set title	Placebo: Start of treatment
Subject analysis set type	Full analysis
Subject analysis set description: Subjects of the Placebo group for baseline visit, whose data are presented in the full analysis.	
Subject analysis set title	Placebo: EoT
Subject analysis set type	Full analysis
Subject analysis set description: Subjects of the Placebo group after 8 weeks of treatment (EoT), whose data are presented in the full analysis.	

Primary: Sleep efficacy (% sleep partial time (SPT)) after 8 weeks of treatment with Rasagiline

End point title	Sleep efficacy (% sleep partial time (SPT)) after 8 weeks of treatment with Rasagiline
End point description:	
End point type	Primary
End point timeframe: between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)	

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	18		
Units: percent				
arithmetic mean (standard deviation)	62.1 (± 11.9)	70.6 (± 13.9)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.024
Method	t-test, 2-sided

Primary: Parkinson’s Disease Sleepiness Scale 2 (PDSS-2) after 8 weeks of treatment with Rasagiline

End point title	Parkinson’s Disease Sleepiness Scale 2 (PDSS-2) after 8 weeks of treatment with Rasagiline

End point description:

End point type	Primary

End point timeframe:

between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	17	17		
Units: points				
arithmetic mean (standard deviation)	20.2 (± 9.6)	20.8 (± 8.9)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.749
Method	t-test, 2-sided

Primary: Sleep efficacy (% time in bed (TIB)) after 8 weeks of treatment with Rasagiline

End point title	Sleep efficacy (% time in bed (TIB)) after 8 weeks of treatment with Rasagiline

End point description: between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)	
End point type	Primary
End point timeframe: 8 weeks	

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	18		
Units: percent				
arithmetic mean (standard deviation)	58.1 (± 14.0)	63.5 (± 15.4)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.097
Method	t-test, 2-sided

Primary: Sleep efficacy (% sleep partial time (SPT)) after 8 weeks of treatment with Placebo

End point title	Sleep efficacy (% sleep partial time (SPT)) after 8 weeks of treatment with Placebo
End point description:	
End point type	Primary
End point timeframe: between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Placebo treatment phase)	

End point values	Placebo: Start of treatment	Placebo: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	7	7		
Units: percent				
arithmetic mean (standard deviation)	82.3 (± 12.3)	79.1 (± 11.9)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Placebo: Start of treatment v Placebo: EoT
Number of subjects included in analysis	14
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.489
Method	t-test, 2-sided

Primary: Parkinson’s Disease Sleepiness Scale 2 (PDSS-2) after 8 weeks of treatment with Placebo

End point title	Parkinson’s Disease Sleepiness Scale 2 (PDSS-2) after 8 weeks of treatment with Placebo

End point description:

End point type	Primary

End point timeframe:

between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Placebo treatment phase)

End point values	Placebo: Start of treatment	Placebo: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	7	7		
Units: Points				
arithmetic mean (standard deviation)	22.2 (± 9.2)	20.0 (± 9.3)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Placebo: EoT v Placebo: Start of treatment
Number of subjects included in analysis	14
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.663
Method	t-test, 2-sided

Primary: Sleep efficacy (% time in bed (TIB)) after 8 weeks of treatment with Placebo

End point title	Sleep efficacy (% time in bed (TIB)) after 8 weeks of treatment with Placebo

End point description:

End point type	Primary

End point timeframe:

between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Placebo treatment phase)

End point values	Placebo: Start of treatment	Placebo: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	7	7		
Units: percent				
arithmetic mean (standard deviation)	76.7 (± 12.9)	69.6 (± 8.6)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Placebo: Start of treatment v Placebo: EoT
Number of subjects included in analysis	14
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.181
Method	t-test, 2-sided

Secondary: Proportion of light sleep stage N1 (%) after 8 weeks of treatment with Rasagiline

End point title	Proportion of light sleep stage N1 (%) after 8 weeks of treatment with Rasagiline

End point description:

End point type	Secondary

End point timeframe:

between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	18		
Units: percent				
arithmetic mean (standard deviation)	22.0 (± 12.2)	17.2 (± 9.8)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.036
Method	t-test, 2-sided

Secondary: Wake time after sleep (from TIB (min)) after 8 weeks of treatment with Rasagiline

End point title	Wake time after sleep (from TIB (min)) after 8 weeks of treatment with Rasagiline

End point description:

End point type	Secondary

End point timeframe:

between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	18		
Units: minutes				
arithmetic mean (standard deviation)	206.2 (± 72.9)	175.8 (± 74.3)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT

Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.048
Method	t-test, 2-sided

Secondary: Arousal-Index (n/h) after 8 weeks of treatment with Rasagiline

End point title	Arousal-Index (n/h) after 8 weeks of treatment with Rasagiline

End point description:

End point type	Secondary

End point timeframe:

between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	18		
Units: number				
arithmetic mean (standard deviation)	49.9 (± 19.1)	43.6 (± 18.1)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.019
Method	t-test, 2-sided

Secondary: Proportion of deep sleep stage N3 (%) after 8 weeks of treatment with Rasagiline

End point title	Proportion of deep sleep stage N3 (%) after 8 weeks of treatment with Rasagiline

End point description:

End point type	Secondary

End point timeframe:

between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	18		
Units: percent				
arithmetic mean (standard deviation)	18.2 (± 10.9)	20.6 (± 11.9)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.194
Method	t-test, 2-sided

Secondary: Proportion of dream (REM) sleep stage (%) after 8 weeks of treatment with Rasagiline

End point title	Proportion of dream (REM) sleep stage (%) after 8 weeks of treatment with Rasagiline

End point description:

End point type	Secondary

End point timeframe:

between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	18		
Units: percent				
arithmetic mean (standard deviation)	6.8 (± 5.7)	8.9 (± 6.0)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.131
Method	t-test, 2-sided

Secondary: Total sleep time (min) after 8 weeks of treatment with Rasagiline

End point title	Total sleep time (min) after 8 weeks of treatment with Rasagiline

End point description:

End point type	Secondary

End point timeframe:

between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	18		
Units: minutes				
arithmetic mean (standard deviation)	286.6 (± 77.2)	310.2 (± 85.0)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.197
Method	t-test, 2-sided

Secondary: Sleep latency (min) after 8 weeks of treatment with Rasagiline

End point title	Sleep latency (min) after 8 weeks of treatment with Rasagiline

End point description:

End point type	Secondary

End point timeframe:

between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	18		
Units: minutes				
arithmetic mean (standard deviation)	19.9 (± 18.6)	26.4 (± 49.0)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.482
Method	t-test, 2-sided

Secondary: REM sleep latency (min) after 8 weeks of treatment with Rasagiline

End point title	REM sleep latency (min) after 8 weeks of treatment with Rasagiline

End point description:

End point type	Secondary

End point timeframe:

between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	14	14		
Units: minutes				
arithmetic mean (standard deviation)	223.3 (± 124.0)	214.2 (± 107.8)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.745
Method	t-test, 2-sided

Secondary: Nocturnal mobility (n) after 8 weeks of treatment with Rasagiline

End point title	Nocturnal mobility (n) after 8 weeks of treatment with Rasagiline

End point description:

End point type	Secondary

End point timeframe:

between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	18		
Units: number				
arithmetic mean (standard deviation)	11.7 (± 6.5)	12.7 (± 8.8)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: EoT v Rasagiline: Start of treatment
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.533
Method	t-test, 2-sided

Secondary: Epworth Sleepiness Scale (EES) after 8 weeks of treatment with Rasagiline

End point title	Epworth Sleepiness Scale (EES) after 8 weeks of treatment with Rasagiline

End point description:

End point type	Secondary

End point timeframe:
between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16	16		
Units: points				
arithmetic mean (standard deviation)	9.4 (± 4.5)	8.5 (± 4.5)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.016
Method	t-test, 2-sided

Secondary: Pittsburgh Sleep Quality Index (PSQI) after 8 weeks of treatment with Rasagiline

End point title	Pittsburgh Sleep Quality Index (PSQI) after 8 weeks of treatment with Rasagiline

End point description:

End point type	Secondary

End point timeframe:
between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	18		
Units: points				
arithmetic mean (standard deviation)	9.4 (± 2.7)	9.3 (± 2.6)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.752
Method	t-test, 2-sided

Secondary: Parkinsons' Daily Quality of Life-39 (PDQ-39) after 8 weeks of treatment with Rasagiline

End point title	Parkinsons' Daily Quality of Life-39 (PDQ-39) after 8 weeks of treatment with Rasagiline

End point description:

End point type	Secondary

End point timeframe:

between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	13	13		
Units: points				
arithmetic mean (standard deviation)	31.2 (± 19.8)	31.0 (± 23.0)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.927
Method	t-test, 2-sided

Secondary: Total Unified Parkinson's disease rating scale (UPDRS) after 8 weeks of treatment with Rasagiline

End point title	Total Unified Parkinson's disease rating scale (UPDRS) after 8 weeks of treatment with Rasagiline

End point description:

End point type	Secondary
End point timeframe: between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)	

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16	16		
Units: points				
arithmetic mean (standard deviation)	30.1 (± 13.7)	29.3 (± 10.4)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.709
Method	t-test, 2-sided

Secondary: Unified Parkinson’s disease rating scale I (UPDRS I) after 8 weeks of treatment with Rasagiline

End point title	Unified Parkinson’s disease rating scale I (UPDRS I) after 8 weeks of treatment with Rasagiline
End point description: UPDRS I: Cognition, mood, behavior	
End point type	Secondary
End point timeframe: between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)	

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	18		
Units: points				
arithmetic mean (standard deviation)	2.1 (± 1.4)	3.2 (± 2.1)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.01
Method	t-test, 2-sided

Secondary: Unified Parkinson’s disease rating scale II (UPDRS II) after 8 weeks of treatment with Rasagiline

End point title	Unified Parkinson’s disease rating scale II (UPDRS II) after 8 weeks of treatment with Rasagiline
End point description: UPDRS II: Activities of daily living	
End point type	Secondary
End point timeframe: between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)	

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	18		
Units: points				
arithmetic mean (standard deviation)	7.5 (± 4.5)	7.8 (± 4.8)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: EoT v Rasagiline: Start of treatment
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.674
Method	t-test, 2-sided

Secondary: Unified Parkinson’s disease rating scale III (UPDRS III) after 8 weeks of treatment with Rasagiline

End point title	Unified Parkinson’s disease rating scale III (UPDRS III) after 8 weeks of treatment with Rasagiline

End point description: UPDRS III: motor score	
End point type	Secondary
End point timeframe: between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)	

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16	16		
Units: points				
arithmetic mean (standard deviation)	17.8 (± 8.5)	15.8 (± 4.8)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.205
Method	t-test, 2-sided

Secondary: Modified Hoehn & Yahr Scale after 8 weeks of treatment with Rasagiline

End point title	Modified Hoehn & Yahr Scale after 8 weeks of treatment with Rasagiline
End point description:	
End point type	Secondary
End point timeframe: between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)	

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	15	15		
Units: points				
arithmetic mean (standard deviation)	2.0 (± 0.7)	1.9 (± 0.8)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.173
Method	t-test, 2-sided

Secondary: Schwab & England Scale ADL after 8 weeks of treatment with Rasagiline	
End point title	Schwab & England Scale ADL after 8 weeks of treatment with Rasagiline
End point description:	
End point type	Secondary
End point timeframe:	
between V2 (end of placebo run-in-phase) and V3 (end of 8 weeks Rasagiline treatment phase)	

End point values	Rasagiline: Start of treatment	Rasagiline: EoT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	14	14		
Units: points				
arithmetic mean (standard deviation)	85.7 (± 8.5)	83.6 (± 13.9)		

Statistical analyses

Statistical analysis title	paired samples t-test
Comparison groups	Rasagiline: Start of treatment v Rasagiline: EoT
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.512
Method	t-test, 2-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From screening visite to telephone follow up visit 4; approx. 25 weeks	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17

Reporting groups	
Reporting group title	Rasagiline
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	Rasagiline	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Lumbar vertebral fracture			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Rasagiline	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 20 (60.00%)	4 / 10 (40.00%)	
Surgical and medical procedures			
Bladder operation			
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Maxillary operation			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	

Nervous system disorders			
Headache			
subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
Dyskinesia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Dystonia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Cognitive deterioration			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Flu like symptoms			
subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	2 / 20 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
Tinnitus			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 20 (5.00%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Vomiting			
subjects affected / exposed	0 / 20 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Pseudohallucination			
subjects affected / exposed	3 / 20 (15.00%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
Insomnia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Libido disorder			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	1 / 20 (5.00%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Arthralgia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	

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