



## Clinical trial results:

### A Proof of Concept Study to Determine the Minimum Effective Dose and to Assess the Efficacy and Safety of Subcutaneous Injections of FPFS-1169 in Parkinson's Disease Patients

#### Summary

EudraCT number	2006-000361-11
Trial protocol	GB
Global end of trial date	30 March 2007

#### Results information

Result version number	v1 (current)
This version publication date	21 July 2022
First version publication date	21 July 2022

#### Trial information

##### Trial identification

Sponsor protocol code	RD 639/24201
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##### Additional study identifiers

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

Notes:

#### Sponsors

Sponsor organisation name	Fujimoto Pharmaceutical Corp
Sponsor organisation address	1-3-40 Nishiotsuka Matsubara, Osaka, Japan, 580-0011
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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 July 2007
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 March 2007
Global end of trial reached?	Yes
Global end of trial date	30 March 2007
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of the trial was:

- To determine the minimum effective dose (MED) and corresponding plasma concentrations of subcutaneous injections of FPFS-1169 in Parkinson's disease patients.

The secondary objectives of the trial were:

- To evaluate the acute effects of subcutaneous injection of FPFS-1169 on the severity of parkinsonian signs in patients with mild to moderately advanced Parkinson's disease.

- To monitor subject safety by means of frequent clinical evaluations and laboratory tests.

Protection of trial subjects:

The study was conducted in accordance with the Declaration of Helsinki (South Africa 1996) and the ABPI Guidelines for Medical Experiments on Non-Patient Human Volunteers - 1988, amended May 1990.), the Guidelines of the International Conference on Harmonisation (ICH) on Good Clinical Practice (GCP) (CPMP/ICH/135/95), as well as the requirements of the European Union Data Protection Directive 95/46/EC, and other applicable regulatory requirements.

Background therapy:

As part of the study, all patients received a standard dose of levodopa/carbidopa on study Day 1 (study period 1).

Evidence for comparator:

N/A - no comparator products were evaluated in this study.

Actual start date of recruitment	21 September 2006
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	United Kingdom: 10
Worldwide total number of subjects	10
EEA total number of subjects	0

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)	4
From 65 to 84 years	6
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

Study recruitment was undertaken in the United Kingdom. The recruitment process began in September 2006 and concluded in February 2007 with 18 patients screening in order to enrol 10 eligible patients.

### Pre-assignment

Screening details:

Patients were screened to the inclusion/exclusion criteria of the protocol. The following assessments were performed: Informed consent, Medical History including current conditions, Physical Exam, Demographics, Height, Weight & BMI, ECG, Vital Signs, Safety Laboratory Testing/Urinalysis & other specific testing related to Parkinson's Disease.

### Period 1

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

Blinding implementation details:

N/A - the study was open label.

### Arms

Are arms mutually exclusive?	No
<b>Arm title</b>	Arm 1 - 3 mg FPFS-1169

Arm description:

This was the lowest dose level evaluated in the study. 2 participants were administered 3.0 mg of FPFS-1169 as a subcutaneous injection.

Arm type	Experimental
Investigational medicinal product name	FPFS-1169
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dosing frequency was one occasion across 5 study periods (Day 1, Day 8, Day 15, Day 22 & Day 29). Dose levels were adjusted per study period based on assessment of previous dose level administered.

<b>Arm title</b>	Arm 2 - 4.5 mg FPFS-1169
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Arm description:

This was the second dose level evaluated in the study. 2 participants were administered 4.5 mg of FPFS-1169 as a subcutaneous injection.

Arm type	Experimental
Investigational medicinal product name	FPFS-1169
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dosing frequency was one occasion across 5 study periods (Day 1, Day 8, Day 15, Day 22 & Day 29). Dose levels were adjusted per study period based on assessment of previous dose level administered.

<b>Arm title</b>	Arm 3 - 6.0 mg FPFS-1169
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Arm description:

This was the third dose level evaluated in the study. 5 participants were administered 6.0 mg of FPFS-1169 as a subcutaneous injection.

Arm type	Experimental
Investigational medicinal product name	FPFS-1169
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dosing frequency was one occasion across 5 study periods (Day 1, Day 8, Day 15, Day 22 & Day 29).  
Dose levels were adjusted per study period based on assessment of previous dose level administered.

<b>Arm title</b>	Arm 4 - 7.5 mg FPFS-1169
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Arm description:

This was the fourth dose level evaluated in the study. 2 participants were administered 7.5 mg of FPFS-1169 as a subcutaneous injection.

Arm type	Experimental
Investigational medicinal product name	FPFS-1169
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dosing frequency was one occasion across 5 study periods (Day 1, Day 8, Day 15, Day 22 & Day 29).  
Dose levels were adjusted per study period based on assessment of previous dose level administered.

<b>Arm title</b>	Arm 5 - 9.0 mg FPFS-1169
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Arm description:

This was the fifth dose level evaluated in the study. 3 participants were administered 9.0 mg of FPFS-1169 as a subcutaneous injection.

Arm type	Experimental
Investigational medicinal product name	FPFS-1169
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dosing frequency was one occasion across 5 study periods (Day 1, Day 8, Day 15, Day 22 & Day 29).  
Dose levels were adjusted per study period based on assessment of previous dose level administered.

<b>Arm title</b>	Arm 6 - 12.0 mg FPFS-1169
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Arm description:

This was the sixth dose level evaluated in the study. 8 participants were administered 12.0 mg of FPFS-1169 as a subcutaneous injection.

Arm type	Experimental
Investigational medicinal product name	FPFS-1169
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dosing frequency was one occasion across 5 study periods (Day 1, Day 8, Day 15, Day 22 & Day 29).  
Dose levels were adjusted per study period based on assessment of previous dose level administered.

<b>Arm title</b>	Arm 7- 15.0 mg FPFS-1169
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Arm description:

This was the seventh dose level evaluated in the study. 2 participants were administered 15.0 mg of FPFS-1169 as a subcutaneous injection.

Arm type	Experimental
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Investigational medicinal product name	FPFS-1169
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dosing frequency was one occasion across 5 study periods (Day 1, Day 8, Day 15, Day 22 & Day 29).  
Dose levels were adjusted per study period based on assessment of previous dose level administered.

<b>Arm title</b>	Arm 8 - 18.0 mg FPFS-1169
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Arm description:

This was the eighth dose level evaluated in the study. 3 participants were administered 18.0 mg of FPFS-1169 as a subcutaneous injection.

Arm type	Experimental
Investigational medicinal product name	FPFS-1169
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dosing frequency was one occasion across 5 study periods (Day 1, Day 8, Day 15, Day 22 & Day 29).  
Dose levels were adjusted per study period based on assessment of previous dose level administered.

<b>Arm title</b>	Arm 9 - 21.0 mg FPFS-1169
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Arm description:

This was the ninth dose level evaluated in the study. 1 participant was administered 21.0 mg of FPFS-1169 as a subcutaneous injection.

Arm type	Experimental
Investigational medicinal product name	FPFS-1169
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dosing frequency was one occasion across 5 study periods (Day 1, Day 8, Day 15, Day 22 & Day 29).  
Dose levels were adjusted per study period based on assessment of previous dose level administered.

<b>Arm title</b>	Arm 10 - 24.0 mg FPFS-1169
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Arm description:

This was the highest dose level evaluated in the study. 1 participant was administered 24.0 mg of FPFS-1169 as a subcutaneous injection.

Arm type	Experimental
Investigational medicinal product name	FPFS-1169
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dosing frequency was one occasion across 5 study periods (Day 1, Day 8, Day 15, Day 22 & Day 29).  
Dose levels were adjusted per study period based on assessment of previous dose level administered.

<b>Number of subjects in period 1</b>	Arm 1 - 3 mg FPFS-1169	Arm 2 - 4.5 mg FPFS-1169	Arm 3 - 6.0 mg FPFS-1169
Started	2	2	5
Completed	2	2	5

<b>Number of subjects in period 1</b>	Arm 4 - 7.5 mg FPFS-1169	Arm 5 - 9.0 mg FPFS-1169	Arm 6 - 12.0 mg FPFS-1169
Started	2	3	8
Completed	2	3	8

<b>Number of subjects in period 1</b>	Arm 7- 15.0 mg FPFS-1169	Arm 8 - 18.0 mg FPFS-1169	Arm 9 - 21.0 mg FPFS-1169
Started	2	3	1
Completed	2	3	1

<b>Number of subjects in period 1</b>	Arm 10 - 24.0 mg FPFS-1169
Started	1
Completed	1

## Baseline characteristics

### Reporting groups

Reporting group title	Overall Trial Period
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Reporting group description: -

Reporting group values	Overall Trial Period	Total	
Number of subjects	10	10	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	4	4	
From 65-84 years	6	6	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	65.9		
standard deviation	± 7.9	-	
Gender categorical			
Units: Subjects			
Female	1	1	
Male	9	9	
Height			
Units: metre			
arithmetic mean	1.74		
standard deviation	± 0.06	-	
Weight			
Units: kilogram(s)			
arithmetic mean	80.6		
standard deviation	± 10.5	-	
Body Mass Index (BMI)			
Units: kilogram(s)/square metre			
arithmetic mean	26.7		
standard deviation	± 2.8	-	



## End points

### End points reporting groups

Reporting group title	Arm 1 - 3 mg FPFS-1169
Reporting group description: This was the lowest dose level evaluated in the study. 2 participants were administered 3.0 mg of FPFS-1169 as a subcutaneous injection.	
Reporting group title	Arm 2 - 4.5 mg FPFS-1169
Reporting group description: This was the second dose level evaluated in the study. 2 participants were administered 4.5 mg of FPFS-1169 as a subcutaneous injection.	
Reporting group title	Arm 3 - 6.0 mg FPFS-1169
Reporting group description: This was the third dose level evaluated in the study. 5 participants were administered 6.0 mg of FPFS-1169 as a subcutaneous injection.	
Reporting group title	Arm 4 - 7.5 mg FPFS-1169
Reporting group description: This was the fourth dose level evaluated in the study. 2 participants were administered 7.5 mg of FPFS-1169 as a subcutaneous injection.	
Reporting group title	Arm 5 - 9.0 mg FPFS-1169
Reporting group description: This was the fifth dose level evaluated in the study. 3 participants were administered 9.0 mg of FPFS-1169 as a subcutaneous injection.	
Reporting group title	Arm 6 - 12.0 mg FPFS-1169
Reporting group description: This was the sixth dose level evaluated in the study. 8 participants were administered 12.0 mg of FPFS-1169 as a subcutaneous injection.	
Reporting group title	Arm 7- 15.0 mg FPFS-1169
Reporting group description: This was the seventh dose level evaluated in the study. 2 participants were administered 15.0 mg of FPFS-1169 as a subcutaneous injection.	
Reporting group title	Arm 8 - 18.0 mg FPFS-1169
Reporting group description: This was the eighth dose level evaluated in the study. 3 participants were administered 18.0 mg of FPFS-1169 as a subcutaneous injection.	
Reporting group title	Arm 9 - 21.0 mg FPFS-1169
Reporting group description: This was the ninth dose level evaluated in the study. 1 participant was administered 21.0 mg of FPFS-1169 as a subcutaneous injection.	
Reporting group title	Arm 10 - 24.0 mg FPFS-1169
Reporting group description: This was the highest dose level evaluated in the study. 1 participant was administered 24.0 mg of FPFS-1169 as a subcutaneous injection.	
Subject analysis set title	Subject 001 MED
Subject analysis set type	Full analysis
Subject analysis set description: This subject analysis set corresponds to the individual subject analysis for assessment of minimum effective dose (MED).	
Subject analysis set title	Subject 002 MED
Subject analysis set type	Full analysis
Subject analysis set description: This subject analysis set corresponds to the individual subject analysis for assessment of minimum effective dose (MED).	
Subject analysis set title	Subject 003 MED

Subject analysis set type	Full analysis
Subject analysis set description: This subject analysis set corresponds to the individual subject analysis for assessment of minimum effective dose (MED).	
Subject analysis set title	Subject 006 MED
Subject analysis set type	Full analysis
Subject analysis set description: This subject analysis set corresponds to the individual subject analysis for assessment of minimum effective dose (MED).	
Subject analysis set title	Subject 007 MED
Subject analysis set type	Full analysis
Subject analysis set description: This subject analysis set corresponds to the individual subject analysis for assessment of minimum effective dose (MED).	
Subject analysis set title	Subject 008 MED
Subject analysis set type	Full analysis
Subject analysis set description: This subject analysis set corresponds to the individual subject analysis for assessment of minimum effective dose (MED).	
Subject analysis set title	Subject 009 MED
Subject analysis set type	Full analysis
Subject analysis set description: This subject analysis set corresponds to the individual subject analysis for assessment of minimum effective dose (MED).	
Subject analysis set title	Subject 010 MED
Subject analysis set type	Full analysis
Subject analysis set description: This subject analysis set corresponds to the individual subject analysis for assessment of minimum effective dose (MED).	

### Primary: Maximum Concentration (Cmax)

End point title	Maximum Concentration (Cmax) <sup>[1]</sup>
End point description:	
End point type	Primary
End point timeframe: Time points for pharmacokinetic evaluation of Cmax in plasma were as follows: pre-dose, 0.5, 1, 2, 4 and 6 hours post dose on Days 8, 15, 22 & 29.	

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: Maximum Concentration (Cmax) were listed as descriptive statistics with no statistical analyses conducted.

End point values	Arm 1 - 3 mg FPFS-1169	Arm 2 - 4.5 mg FPFS-1169	Arm 3 - 6.0 mg FPFS-1169	Arm 4 - 7.5 mg FPFS-1169
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	5	2
Units: ng/mL				
arithmetic mean (full range (min-max))	1.937 (1.139 to 2.734)	2.080 (1.435 to 2.725)	3.934 (2.329 to 6.594)	3.901 (2.800 to 5.002)

End point values	Arm 5 - 9.0 mg FPFS-1169	Arm 6 - 12.0 mg FPFS-1169	Arm 7- 15.0 mg FPFS-1169	Arm 8 - 18.0 mg FPFS-1169
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	8	2	3
Units: ng/mL				
arithmetic mean (full range (min-max))	6.270 (2.784 to 9.483)	9.213 (4.221 to 15.882)	6.206 (5.580 to 6.831)	7.849 (6.056 to 10.499)

End point values	Arm 9 - 21.0 mg FPFS-1169	Arm 10 - 24.0 mg FPFS-1169		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: ng/mL				
arithmetic mean (full range (min-max))	16.653 (16.653 to 16.653)	22.846 (22.846 to 22.846)		

## Statistical analyses

No statistical analyses for this end point

### Primary: Time to maximum observed concentration (Tmax)

End point title	Time to maximum observed concentration (Tmax) <sup>[2]</sup>
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End point description:

End point type	Primary
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End point timeframe:

Time points for pharmacokinetic evaluation of Tmax in plasma were as follows: pre-dose, 0.5, 1, 2, 4 and 6 hours post dose on Days 8, 15, 22 & 29.

Notes:

[2] - 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: Time to maximum observed concentration (Tmax) were listed as descriptive statistics with no statistical analyses conducted.

End point values	Arm 1 - 3 mg FPFS-1169	Arm 2 - 4.5 mg FPFS-1169	Arm 3 - 6.0 mg FPFS-1169	Arm 4 - 7.5 mg FPFS-1169
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	5	2
Units: hour				
median (full range (min-max))	0.50 (0.50 to 0.50)	0.75 (0.50 to 1.00)	0.50 (0.50 to 1.00)	1.25 (0.50 to 2.00)

End point values	Arm 5 - 9.0 mg FPFS-1169	Arm 6 - 12.0 mg FPFS-1169	Arm 7- 15.0 mg FPFS-1169	Arm 8 - 18.0 mg FPFS-1169
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	8	2	3
Units: hour				

median (full range (min-max))	0.50 (0.50 to 2.00)	0.50 (0.50 to 1.00)	0.75 (0.50 to 1.00)	2.00 (0.50 to 4.00)
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<b>End point values</b>	Arm 9 - 21.0 mg FPFS-1169	Arm 10 - 24.0 mg FPFS-1169		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: hour				
median (full range (min-max))	1.00 (1.00 to 1.00)	0.50 (0.50 to 0.50)		

## Statistical analyses

No statistical analyses for this end point

### Primary: Area under the curve from the time of dosing to the time of the last measurable concentration (AUC0-t)

End point title	Area under the curve from the time of dosing to the time of the last measurable concentration (AUC0-t) <sup>[3]</sup>
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End point description:

End point type	Primary
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End point timeframe:

Time points for pharmacokinetic evaluation of AUC0-t in plasma were as follows: pre-dose, 0.5, 1, 2, 4 and 6 hours post dose on Days 8, 15, 22 & 29.

Notes:

[3] - 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: Area under the curve from the time of dosing to the time of the last measurable concentration (AUC0-t) were listed as descriptive statistics with no statistical analyses conducted.

<b>End point values</b>	Arm 1 - 3 mg FPFS-1169	Arm 2 - 4.5 mg FPFS-1169	Arm 3 - 6.0 mg FPFS-1169	Arm 4 - 7.5 mg FPFS-1169
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	5	2
Units: ng/ml/h				
arithmetic mean (full range (min-max))	5.872 (4.422 to 7.321)	6.342 (5.512 to 7.172)	14.003 (7.549 to 21.016)	16.403 (13.724 to 19.083)

<b>End point values</b>	Arm 5 - 9.0 mg FPFS-1169	Arm 6 - 12.0 mg FPFS-1169	Arm 7- 15.0 mg FPFS-1169	Arm 8 - 18.0 mg FPFS-1169
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	8	2	3
Units: ng/ml/h				
arithmetic mean (full range (min-max))	22.615 (14.260 to 37.500)	25.392 (14.085 to 33.734)	30.872 (28.936 to 32.808)	36.320 (28.768 to 47.607)

<b>End point values</b>	Arm 9 - 21.0 mg FPFS-1169	Arm 10 - 24.0 mg FPFS-1169		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: ng/ml/h				
arithmetic mean (full range (min-max))	70.610 (70.610 to 70.610)	73.802 (73.802 to 73.802)		

## Statistical analyses

No statistical analyses for this end point

### Primary: Minimum Effective Dose

End point title	Minimum Effective Dose <sup>[4]</sup>
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End point description:

End point type	Primary
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End point timeframe:

Assessment of Minimum Effective Dose was carried out from Day 1 through to Day 29.

Notes:

[4] - 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: Minimum Effective Dose were listed as descriptive statistics with no statistical analyses conducted.

<b>End point values</b>	Subject 001 MED	Subject 002 MED	Subject 003 MED	Subject 006 MED
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	1	1	1
Units: milligram(s)				
number (not applicable)	12	6	7.5	15

<b>End point values</b>	Subject 007 MED	Subject 008 MED	Subject 009 MED	Subject 010 MED
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	1	1	1
Units: milligram(s)				
number (not applicable)	18	24	4.5	9

## Statistical analyses

No statistical analyses for this end point

### Primary: Maximum Concentration (Cmax) - Minimum Effective Dose

End point title	Maximum Concentration (Cmax) - Minimum Effective Dose <sup>[5]</sup>
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End point description:

End point type	Primary
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End point timeframe:

Time points for pharmacokinetic evaluation of Cmax in plasma were as follows: pre-dose, 0.5, 1, 2, 4 and 6 hours post dose on Days 8, 15, 22 & 29.

Notes:

[5] - 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: Maximum Concentration (Cmax) - Minimum Effective Dose were listed as descriptive statistics with no statistical analyses conducted.

End point values	Subject 001 MED	Subject 002 MED	Subject 003 MED	Subject 006 MED
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	1	1	1
Units: ng/mL				
number (not applicable)	12.836	5.827	5.002	5.580

End point values	Subject 007 MED	Subject 008 MED	Subject 009 MED	Subject 010 MED
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	1	1	1
Units: ng/mL				
number (not applicable)	6.056	22.846	1.435	2.784

### Statistical analyses

No statistical analyses for this end point

### Primary: Area under the curve from the time of dosing to the time of the last measurable concentration (AUC0-t) - Minimum Effective Dose

End point title	Area under the curve from the time of dosing to the time of the last measurable concentration (AUC0-t) - Minimum Effective Dose <sup>[6]</sup>
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End point description:

End point type	Primary
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End point timeframe:

Time points for pharmacokinetic evaluation of AUC0-t in plasma were as follows: pre-dose, 0.5, 1, 2, 4 and 6 hours post dose on Days 8, 15, 22 & 29.

Notes:

[6] - 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: Area under the curve from the time of dosing to the time of the last measurable concentration (AUC0-t) - Minimum Effective Dose were listed as descriptive statistics with no statistical

analyses conducted.

End point values	Subject 001 MED	Subject 002 MED	Subject 003 MED	Subject 006 MED
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	1	1	1
Units: ng/mL/h				
number (not applicable)	33.734	18.030	19.083	28.936

End point values	Subject 007 MED	Subject 008 MED	Subject 009 MED	Subject 010 MED
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	1	1	1
Units: ng/mL/h				
number (not applicable)	32.586	73.802	5.512	14.260

### Statistical analyses

No statistical analyses for this end point

### Secondary: Maximum Mean Change from Baseline (UPDRS Part III) - Minimum Effective Dose

End point title	Maximum Mean Change from Baseline (UPDRS Part III) - Minimum Effective Dose
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End point description:

End point type	Secondary
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End point timeframe:

Evaluation of UPDRS and changes from baseline were assessed at set timepoints from Day 1 through to the end of study.

End point values	Subject 001 MED	Subject 002 MED	Subject 003 MED	Subject 006 MED
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	1	1	1
Units: UPDRS Score				
number (not applicable)	-8.0	-3.0	-2.0	-4.0

End point values	Subject 007 MED	Subject 008 MED	Subject 009 MED	Subject 010 MED
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Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	1	1	1
Units: UPDRS Score				
number (not applicable)	-8.0	-2.0	-6.0	-7.0

## Statistical analyses

No statistical analyses for this end point

## Secondary: Maximum Improvement in Timed Walk Test

End point title	Maximum Improvement in Timed Walk Test
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End point description:

End point type	Secondary
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End point timeframe:

Evaluation of improvement in timed walk test were assessed at set timepoints from Day 1 through to the end of study.

End point values	Arm 1 - 3 mg FPFS-1169	Arm 2 - 4.5 mg FPFS-1169	Arm 3 - 6.0 mg FPFS-1169	Arm 4 - 7.5 mg FPFS-1169
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	5	2
Units: second				
number (not applicable)	0.1	0.7	0.6	1.4

End point values	Arm 5 - 9.0 mg FPFS-1169	Arm 6 - 12.0 mg FPFS-1169	Arm 7- 15.0 mg FPFS-1169	Arm 8 - 18.0 mg FPFS-1169
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	8	2	3
Units: second				
number (not applicable)	1.4	0.88	0.65	0.47

End point values	Arm 9 - 21.0 mg FPFS-1169	Arm 10 - 24.0 mg FPFS-1169		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: second				
number (not applicable)	0.2	0.7		



## Statistical analyses

No statistical analyses for this end point

### Secondary: Time of Maximum Improvement - Timed Walk Test

End point title	Time of Maximum Improvement - Timed Walk Test
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End point description:

End point type	Secondary
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End point timeframe:

Evaluation of improvement in timed walk test were assessed at set timepoints from Day 1 through to the end of study.

End point values	Arm 1 - 3 mg FPFS-1169	Arm 2 - 4.5 mg FPFS-1169	Arm 3 - 6.0 mg FPFS-1169	Arm 4 - 7.5 mg FPFS-1169
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	5	2
Units: hour				
number (not applicable)	6.0	0.5	6.0	6.0

End point values	Arm 5 - 9.0 mg FPFS-1169	Arm 6 - 12.0 mg FPFS-1169	Arm 7- 15.0 mg FPFS-1169	Arm 8 - 18.0 mg FPFS-1169
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	8	2	3
Units: hour				
number (not applicable)	1.0	5.0	2.0	3.0

End point values	Arm 9 - 21.0 mg FPFS-1169	Arm 10 - 24.0 mg FPFS-1169		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: hour				
number (not applicable)	0.5	0.5		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Treatment Emergent Adverse Events

End point title	Treatment Emergent Adverse Events
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End point description:

This endpoint relates to the number of patients who reported a treatment emergent adverse event (TEAEs) during the study.

There were a total of 18 treatment emergent adverse events reported during the study. Of these, 16 were reported following administration of subcutaneous injections of FPFS-1169. Two adverse events were reported following the standard dose of levodopa/carbidopa on Study Day 1. One of the treatment emergent adverse events was considered to be moderate in severity. All other events were considered to be mild in severity.

End point type	Secondary
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End point timeframe:

Collection of treatment emergent adverse events occurred from the point of dose administration until completion of the end of study.

End point values	Arm 1 - 3 mg FPFS-1169	Arm 2 - 4.5 mg FPFS-1169	Arm 3 - 6.0 mg FPFS-1169	Arm 4 - 7.5 mg FPFS-1169
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	5	2
Units: Number of Subjects	1	0	2	0

End point values	Arm 5 - 9.0 mg FPFS-1169	Arm 6 - 12.0 mg FPFS-1169	Arm 7- 15.0 mg FPFS-1169	Arm 8 - 18.0 mg FPFS-1169
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	8	2	3
Units: Number of Subjects	1	4	0	1

End point values	Arm 9 - 21.0 mg FPFS-1169	Arm 10 - 24.0 mg FPFS-1169		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: Number of Subjects	1	0		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Laboratory Parameters

End point title	Laboratory Parameters
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End point description:

This primary endpoint will report the number of subjects who had out of range results for any of the Laboratory Parameters (biochemistry, haematology & urinalysis).

This endpoint will only report number of subjects who had out of range results from Day 1 onwards following administration of the IMP until the completion of the post study visit.

There were no clinically significant biochemistry, haematology or urinalysis results during the study.

End point type	Secondary
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End point timeframe:

Laboratory Parameters (biochemistry, haematology and urinalysis) were measured at set time points from Day 1 until the end of the study.

End point values	Arm 1 - 3 mg FPFS-1169	Arm 2 - 4.5 mg FPFS-1169	Arm 3 - 6.0 mg FPFS-1169	Arm 4 - 7.5 mg FPFS-1169
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	5	2
Units: Number of Subjects	2	2	5	2

End point values	Arm 5 - 9.0 mg FPFS-1169	Arm 6 - 12.0 mg FPFS-1169	Arm 7- 15.0 mg FPFS-1169	Arm 8 - 18.0 mg FPFS-1169
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	8	2	3
Units: Number of Subjects	3	8	2	3

End point values	Arm 9 - 21.0 mg FPFS-1169	Arm 10 - 24.0 mg FPFS-1169		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: Number of Subjects	1	1		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Vital Signs Parameters

End point title	Vital Signs Parameters
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End point description:

This primary endpoint will report the number of subjects who had out of range results for any of the Vital Sign Parameters (systolic and diastolic blood pressure, pulse, oral temperature & respiration rate).

This endpoint will only report number of subjects who had out of range results from Day 1 onwards following administration of the IMP until the completion of the post study visit.

There were no clinically significant changes in vital signs parameters during the study at any dose level evaluated.

End point type	Secondary
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End point timeframe:

Vital Sign Parameters (systolic and diastolic blood pressure, pulse, respiration rate & oral temperature) were measured at set time points from Day 1 until the end of the study.

<b>End point values</b>	Arm 1 - 3 mg FPFS-1169	Arm 2 - 4.5 mg FPFS-1169	Arm 3 - 6.0 mg FPFS-1169	Arm 4 - 7.5 mg FPFS-1169
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	5	2
Units: Number of Subjects	2	2	5	2

<b>End point values</b>	Arm 5 - 9.0 mg FPFS-1169	Arm 6 - 12.0 mg FPFS-1169	Arm 7- 15.0 mg FPFS-1169	Arm 8 - 18.0 mg FPFS-1169
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	8	2	3
Units: Number of Subjects	3	8	2	3

<b>End point values</b>	Arm 9 - 21.0 mg FPFS-1169	Arm 10 - 24.0 mg FPFS-1169		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: Number of Subjects	1	1		

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Adverse events were reported from the time of signing informed consent until completion of the end of the study.

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	8.0
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### Reporting groups

Reporting group title	Arm 1 - 3 mg FPFS-1169
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Reporting group description:

This was the lowest dose level evaluated in the study. 2 participants were administered 3.0 mg of FPFS-1169 as a subcutaneous injection.

Reporting group title	Arm 2 - 4.5 mg FPFS-1169
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Reporting group description:

This was the second dose level evaluated in the study. 2 participants were administered 4.5 mg of FPFS-1169 as a subcutaneous injection.

Reporting group title	Arm 3 - 6.0 mg FPFS-1169
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Reporting group description:

This was the third dose level evaluated in the study. 5 participants were administered 6.0 mg of FPFS-1169 as a subcutaneous injection.

Reporting group title	Arm 4 - 7.5 mg FPFS-1169
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Reporting group description:

This was the fourth dose level evaluated in the study. 2 participants were administered 7.5 mg of FPFS-1169 as a subcutaneous injection.

Reporting group title	Arm 5 - 9.0 mg FPFS-1169
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Reporting group description:

This was the fifth dose level evaluated in the study. 3 participants were administered 9.0 mg of FPFS-1169 as a subcutaneous injection.

Reporting group title	Arm 6 - 12.0 mg FPFS-1169
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Reporting group description:

This was the sixth dose level evaluated in the study. 8 participants were administered 12.0 mg of FPFS-1169 as a subcutaneous injection.

Reporting group title	Arm 7- 15.0 mg FPFS-1169
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Reporting group description:

This was the seventh dose level evaluated in the study. 2 participants were administered 15.0 mg of FPFS-1169 as a subcutaneous injection.

Reporting group title	Arm 8 - 18.0 mg FPFS-1169
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Reporting group description:

This was the eighth dose level evaluated in the study. 3 participants were administered 18.0 mg of FPFS-1169 as a subcutaneous injection.

Reporting group title	Arm 9 - 21.0 mg FPFS-1169
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Reporting group description:

This was the ninth dose level evaluated in the study. 1 participant was administered 21.0 mg of FPFS-1169 as a subcutaneous injection.

Reporting group title	Arm 10 - 24.0 mg FPFS-1169
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Reporting group description:

This was the highest dose level evaluated in the study. 1 participant was administered 24.0 mg of FPFS-1169 as a subcutaneous injection.

Reporting group title	Baseline Dosing - Levodopa/Carbadopa
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Reporting group description:

This reporting group corresponds to all patients who reported an adverse event following administration

<b>Serious adverse events</b>	Arm 1 - 3 mg FPFS-1169	Arm 2 - 4.5 mg FPFS-1169	Arm 3 - 6.0 mg FPFS-1169
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

<b>Serious adverse events</b>	Arm 4 - 7.5 mg FPFS-1169	Arm 5 - 9.0 mg FPFS-1169	Arm 6 - 12.0 mg FPFS-1169
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

<b>Serious adverse events</b>	Arm 7- 15.0 mg FPFS-1169	Arm 8 - 18.0 mg FPFS-1169	Arm 9 - 21.0 mg FPFS-1169
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

<b>Serious adverse events</b>	Arm 10 - 24.0 mg FPFS-1169	Baseline Dosing - Levodopa/Carbadopa	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

<b>Non-serious adverse events</b>	Arm 1 - 3 mg FPFS-1169	Arm 2 - 4.5 mg FPFS-1169	Arm 3 - 6.0 mg FPFS-1169
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	2 / 5 (40.00%)

Investigations			
Blood glucose abnormal subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 5 (0.00%) 0
Blood urea increased subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 5 (0.00%) 0
Blood creatine increased subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 5 (0.00%) 0
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	1 / 5 (20.00%) 1
Parosmia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 5 (0.00%) 0
General disorders and administration site conditions			
Feeling abnormal subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 1	0 / 2 (0.00%) 0	1 / 5 (20.00%) 1
Gastrointestinal disorders			
Diarrhoea subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 5 (0.00%) 0
Skin and subcutaneous tissue disorders			
Rash subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 5 (0.00%) 0
Renal and urinary disorders			
Dysuria subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 5 (0.00%) 0
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 5 (0.00%) 0
Musculoskeletal and connective tissue			

disorders			
Groin pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Increased appetite			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

<b>Non-serious adverse events</b>	Arm 4 - 7.5 mg FPFS-1169	Arm 5 - 9.0 mg FPFS-1169	Arm 6 - 12.0 mg FPFS-1169
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	4 / 8 (50.00%)
Investigations			
Blood glucose abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Parosmia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Feeling abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			



Diarrhoea subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Renal and urinary disorders Dysuria subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Musculoskeletal and connective tissue disorders Groin pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0
Infections and infestations Gastroenteritis subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Metabolism and nutrition disorders Increased appetite subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0

<b>Non-serious adverse events</b>	Arm 7- 15.0 mg FPFS-1169	Arm 8 - 18.0 mg FPFS-1169	Arm 9 - 21.0 mg FPFS-1169
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 1 (100.00%)
Investigations Blood glucose abnormal subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 3 (33.33%) 1	0 / 1 (0.00%) 0
Blood urea increased subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 3 (33.33%) 1	0 / 1 (0.00%) 0

Blood creatine increased subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 3 (33.33%) 1	0 / 1 (0.00%) 0
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Parosmia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 3 (33.33%) 1	0 / 1 (0.00%) 0
General disorders and administration site conditions Feeling abnormal subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	1 / 1 (100.00%) 1
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Renal and urinary disorders Dysuria subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	1 / 1 (100.00%) 1
Musculoskeletal and connective tissue disorders Groin pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Infections and infestations Gastroenteritis			

subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Metabolism and nutrition disorders Increased appetite subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 3 (33.33%) 1	0 / 1 (0.00%) 0

<b>Non-serious adverse events</b>	Arm 10 - 24.0 mg FPFS-1169	Baseline Dosing - Levodopa/Carbadopa	
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 1 (0.00%)	2 / 10 (20.00%)	
Investigations Blood glucose abnormal subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 10 (10.00%) 1	
Blood urea increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 10 (0.00%) 0	
Blood creatine increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 10 (0.00%) 0	
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 10 (0.00%) 0	
Parosmia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 10 (0.00%) 0	
General disorders and administration site conditions Feeling abnormal subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 10 (0.00%) 0	
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 10 (0.00%) 0	
Skin and subcutaneous tissue disorders			

Rash subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 10 (0.00%) 0	
Renal and urinary disorders Dysuria subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 10 (0.00%) 0	
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 10 (0.00%) 0	
Musculoskeletal and connective tissue disorders Groin pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 10 (0.00%) 0	
Infections and infestations Gastroenteritis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 10 (10.00%) 1	
Metabolism and nutrition disorders Increased appetite subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 10 (0.00%) 0	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 May 2006	Protocol Amendment No. 1 (dated 25 May 2006) was generated to document the change to the Research Site used for the study. This was due to the superior facilities available at the purpose built Clinical Research Facility.  This amendment also documented additions to the list of co-investigators, inclusion of a follow-up telephone call for the purposes of monitoring the safety and well-being of the subjects, removal of pharmacokinetic samples and local tolerability assessments on Study Day 1 (standard levodopa/carbidopa dose) & correction of other minor typographical errors.
28 February 2007	Protocol Amendment No. 2 (dated 28 Feb 2007) documented the addition of a further Investigator.

Notes:

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### 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.

N/A

Notes: