



## Clinical trial results:

### A randomised-controlled trial of donepezil for motor recovery in acute stroke

#### Summary

EudraCT number	2010-024048-14
Trial protocol	GB
Global end of trial date	01 January 2015

#### Results information

Result version number	v1 (current)
This version publication date	26 January 2020
First version publication date	26 January 2020
Summary attachment (see zip file)	Statement (end of study_2010-024048-14_imperial.docx)

#### Trial information

##### Trial identification

Sponsor protocol code	CRO1793
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01442766
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	Imperial College London
Sponsor organisation address	South Kensington Campus, London, United Kingdom, SW7 2AZ
Public contact	Paul Bentley, Imperial College London, p.bentley@imperial.ac.uk
Scientific contact	Paul Bentley, Imperial College London, p.bentley@imperial.ac.uk

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:

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**Results analysis stage**

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Analysis stage	Final
Date of interim/final analysis	01 January 2015
Is this the analysis of the primary completion data?	No

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Global end of trial reached?	Yes
Global end of trial date	01 January 2015
Was the trial ended prematurely?	Yes

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Notes:

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**General information about the trial**

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Main objective of the trial:

Can a 12-week course of donepezil improve motor recovery in acute stroke?

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 December 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

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Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

Country: Number of subjects enrolled	United Kingdom: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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Notes:

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**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)	99999
From 65 to 84 years	0
85 years and over	0

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## Subject disposition

### Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 participants, this trial was discontinued due to lack of financial support

### Pre-assignment

Screening details:

N/A

### Period 1

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

### Arms

Arm title	Donepezil
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Donepezil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

5mg

<b>Number of subjects in period 1</b>	Donepezil
Started	99999
Completed	99999

## Baseline characteristics

### Reporting groups

Reporting group title	Overall Trial
Reporting group description: -	

Reporting group values	Overall Trial	Total	
Number of subjects	99999	99999	
Age categorical Units: Subjects			
Adults (18-64 years)	99999	99999	
Age continuous Units: years median standard deviation	0 ± 0	-	
Gender categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

## End points

### End points reporting groups

Reporting group title	Donepezil
Reporting group description: -	

### Primary: Overall

End point title	Overall <sup>[1]</sup>
End point description: This trial was discontinued due to lack of financial support, no results available	
End point type	Primary
End point timeframe: N/A	

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: No results available

End point values	Donepezil			
Subject group type	Reporting group			
Number of subjects analysed	99999			
Units: 0				
number (not applicable)	0			

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

N/A

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	0
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### Reporting groups

Reporting group title	Overall trial
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Reporting group description: -

Serious adverse events	Overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: No adverse events occurred

## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported