



Clinical trial results:

Clinical Trial to Explore Treatment Effects of Ginkgo biloba Extract EGb 761® in Patients with Different Types of Vertigo and Effect Modification by Type of Vertigo, Chronicity and Concomitant Pathologies

Summary

EudraCT number	2016-000316-15
Trial protocol	PL
Global end of trial date	12 June 2018

Results information

Result version number	v1 (current)
This version publication date	12 October 2019
First version publication date	12 October 2019
Summary attachment (see zip file)	523079.01.114 Summary of results for Eudra CT database V1.0 2019_09_25 (523079.01.114_SummaryOfResults_EUDRA_CT_V1.0_

Trial information

Trial identification

Sponsor protocol code	523079.01.114
-----------------------	---------------

Additional study identifiers

ISRCTN number	ISRCTN83227991
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Dr. Willmar Schwabe GmbH & Co. KG
Sponsor organisation address	Willmar-Schwabe-Str. 4, Karlsruhe, Germany, 76227
Public contact	Head Clinical Research Department, Dr. Willmar Schwabe GmbH & Co. KG, 0049 7214005573,
Scientific contact	Head Clinical Research Department, Dr. Willmar Schwabe GmbH & Co. KG, 0049 7214005573,

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	23 July 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 June 2018
Global end of trial reached?	Yes
Global end of trial date	12 June 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To explore whether causes, risk factors, chronicity of vertigo and accompanying features influence the treatment effect of EGb 761® in terms of improvement and response rates
- To identify groups of patients that benefit most of EGb 761®

Protection of trial subjects:

Possibility to withdraw informed consent. Monitoring of adverse events and laboratory parameters.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 October 2016
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	Poland: 206
Worldwide total number of subjects	206
EEA total number of subjects	206

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)	160
From 65 to 84 years	46
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited in twelve investigational sites in Poland.

Pre-assignment

Screening details:

Twenty seven patients did not receive the investigational product since they were classified as screening failures.

Pre-assignment period milestones

Number of subjects started	206
Number of subjects completed	179

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Screening Failures: 27
----------------------------	------------------------

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	Baseline

Arm description:

Baseline before starting treatment with EGb 761®

Arm type	Baseline
No investigational medicinal product assigned in this arm	
Arm title	EGb 761®

Arm description:

Investigational medical product containing EGb 761®, two film-coated tablets of 120 mg Ginkgo biloba extract

Arm type	Experimental
Investigational medicinal product name	EGb 761®
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

1 film-coated tablet 2 times per day for 12 consecutive weeks.

Number of subjects in period 1	Baseline	EGb 761®
Started	179	179
Completed	179	169
Not completed	0	10
Consent withdrawn by subject	-	4
Adverse event, non-fatal	-	1
Laboratory results at baseline	-	2
Lost to follow-up	-	3

Baseline characteristics

Reporting groups^[1]

Reporting group title	Treatment period (overall period)
-----------------------	-----------------------------------

Reporting group description:

In total, 179 subjects received the investigational treatment.

Notes:

[1] - The number of subjects reported to be in the baseline period is not equal to the worldwide number of subjects enrolled in the trial. It is expected that these numbers will be the same.

Justification: Some patients were not included into the analysis set due to drop out without having treatment

Reporting group values	Treatment period (overall period)	Total	
Number of subjects	179	179	
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)	137	137	
From 65-84 years	42	42	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	52.2		
standard deviation	± 14.5	-	
Gender categorical Units: Subjects			
Female	139	139	
Male	40	40	

Subject analysis sets

Subject analysis set title	Full Analysis Set
----------------------------	-------------------

Subject analysis set type	Full analysis
---------------------------	---------------

Subject analysis set description:

The full analysis set (FAS) includes all patients who took EGb 761® treatment and have at least one value of one of the most important variables to describe treatment effects assessed after baseline.

Subject analysis set title	Safety Evaluation Set
----------------------------	-----------------------

Subject analysis set type	Safety analysis
---------------------------	-----------------

Subject analysis set description:

The safety evaluable set (SES) comprises all patients having taken at least one tablet of EGb 761®.

Reporting group values	Full Analysis Set	Safety Evaluation Set	
Number of subjects	174	179	
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)	133	137	
From 65-84 years	41	42	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	52.2	52.2	
standard deviation	± 14.5	± 14.5	
Gender categorical			
Units: Subjects			
Female	135	139	
Male	39	40	

End points

End points reporting groups

Reporting group title	Baseline
Reporting group description: Baseline before starting treatment with EGb 761®	
Reporting group title	EGb 761®
Reporting group description: Investigational medical product containing EGb 761®, two film-coated tablets of 120 mg Ginkgo biloba extract	
Subject analysis set title	Full Analysis Set
Subject analysis set type	Full analysis
Subject analysis set description: The full analysis set (FAS) includes all patients who took EGb 761® treatment and have at least one value of one of the most important variables to describe treatment effects assessed after baseline.	
Subject analysis set title	Safety Evaluation Set
Subject analysis set type	Safety analysis
Subject analysis set description: The safety evaluable set (SES) comprises all patients having taken at least one tablet of EGb 761®.	

Primary: Primary end point

End point title	Primary end point ^[1]
End point description: This document in its section "End points" specifies commercially confidential information of Dr. Willmar Schwabe GmbH & Co. KG, Karlsruhe referred to in Article 81 Section (4) b) Regulation (EU) 536/2014 that is a trade secret and released by the holder for purposes of Regulation (EU) 536/2014 only under the condition of confidence. Trade secrets may not - even in part - be published or released to third parties other than to competent authorities without express permission of the trade secret holder.	
End point type	Primary
End point timeframe: Week 0 - week 12	

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 document for a complete description of the statistical methods and results.

There were no primary end points defined for analysis. Because at least one primary end point is required to be entered into the database, the outcome variable presented here have been chosen to this purpose.

Statistical analyses were conducted descriptively for all end points. Please refer to the attached summary of results for details.

End point values	Baseline	EGb 761®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	174	174		
Units: points				
median (inter-quartile range (Q1-Q3))	9999.99 (9999.99 to 9999.99)	9999.99 (9999.99 to 9999.99)		

Statistical analyses

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

15 weeks

Adverse event reporting additional description:

Non-serious adverse events occurred in 33 patients. However, no incidence of preferred terms of adverse events was higher than the threshold of 5%.

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	19.0
--------------------	------

Reporting groups

Reporting group title	After risk phase
-----------------------	------------------

Reporting group description:

After risk phase

Reporting group title	Between begin of study and begin of 1st study period
-----------------------	--

Reporting group description:

Before Tretament

Reporting group title	Treatment with EGb 761® 240 mg
-----------------------	--------------------------------

Reporting group description:

Study Drug

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 (AE) with an incidence higher than the threshold of 5% occurred during the trial.

Serious adverse events	After risk phase	Between begin of study and begin of 1st study period	Treatment with EGb 761® 240 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 179 (0.56%)	0 / 179 (0.00%)	1 / 179 (0.56%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Blood sodium increased			
subjects affected / exposed	1 / 179 (0.56%)	0 / 179 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Tibia fracture			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	After risk phase	Between begin of study and begin of 1st study period	Treatment with EGb 761® 240 mg
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	0 / 179 (0.00%)

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