



Clinical trial results:

A Randomized, Double-Blind, Placebo-Controlled Proof-of-Concept Study to Assess the Safety and Efficacy of Elezanumab in Acute Ischemic Stroke

Summary

EudraCT number	2019-003753-29
Trial protocol	ES
Global end of trial date	23 December 2024

Results information

Result version number	v1 (current)
This version publication date	28 November 2025
First version publication date	28 November 2025

Trial information

Trial identification

Sponsor protocol code	M19-148
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04309474
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AbbVie Deutschland GmbH & Co. KG
Sponsor organisation address	AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, United Kingdom, SL6 4UB
Public contact	Global Medical Services, AbbVie, Global Medical Services, AbbVie, 001 8006339110, abbvieclinicaltrials@abbvie.com
Scientific contact	Global Medical Services, AbbVie, Global Medical Services, AbbVie, 001 8006339110, abbvieclinicaltrials@abbvie.com

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 December 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 April 2024
Global end of trial reached?	Yes
Global end of trial date	23 December 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of the study was to assess the efficacy, safety, tolerability, and PK of elezanumab in subjects with Acute Ischemic Stroke (AIS).

Protection of trial subjects:

Prior to any study-related screening procedures being performed on the subject or any medications being discontinued by the subject in order to participate in this study, the informed consent statement will be reviewed, signed, and dated by the subject or their legally authorized representative, the person who administered the informed consent, and any other signatories according to local requirements. A copy of the signed informed consent will be given to the subject and the original will be placed in the subject's medical record.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 November 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 4
Country: Number of subjects enrolled	Canada: 21
Country: Number of subjects enrolled	Japan: 12
Country: Number of subjects enrolled	Korea, Republic of: 4
Country: Number of subjects enrolled	Spain: 33
Country: Number of subjects enrolled	United States: 47
Worldwide total number of subjects	121
EEA total number of subjects	33

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)	40
From 65 to 84 years	72
85 years and over	9

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 121 subjects were randomized at 30 sites in 6 countries: Australia, Canada, Japan, South Korea, Spain, and the US, and 119 subjects received study treatment. Eighty of 121 randomized subjects completed study treatment.

Period 1

Period 1 title	Overall Study Period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants will receive placebo for elezanumab via Intravenous (IV) infusion.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The solution contained in the study vial(s) will be diluted in 250 mL of 0.9% Sodium Chloride Injection/Solution for Infusion. Study drug will be administered intravenously every 4 weeks through Week 48 for a total of 13 doses.

Arm title	Elezanumab
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Arm description:

Participants will receive elezanumab 1800 mg via Intravenous (IV) infusion.

Arm type	Experimental
Investigational medicinal product name	Elezanumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The solution contained in the study vial(s) will be diluted in 250 mL of 0.9% Sodium Chloride Injection/Solution for Infusion. Study drug will be administered intravenously every 4 weeks through Week 48 for a total of 13 doses. Total dose is 1800 mg.

Number of subjects in period 1 ^[1]	Placebo	Elezanumab
Started	60	59
Completed	39	41
Not completed	21	18
Consent withdrawn by subject	6	9
Adverse event	4	1
Lost to follow-up	1	2
Not disclosed	10	6

Notes:

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

Justification: A total of 121 subjects were randomized for this study, but only 119 subjects received study treatment.

Baseline characteristics

Reporting groups

Reporting group title	Placebo
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Reporting group description:

Participants will receive placebo for elezanumab via Intravenous (IV) infusion.

Reporting group title	Elezanumab
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Reporting group description:

Participants will receive elezanumab 1800 mg via Intravenous (IV) infusion.

Reporting group values	Placebo	Elezanumab	Total
Number of subjects	60	59	119
Age categorical			
Units: Subjects			
< 70 years	27	25	52
70 to < 80 years	18	19	37
≥ 80 years	15	15	30
Gender categorical			
Units: Subjects			
Female	32	24	56
Male	28	35	63
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	7	5	12
Not Hispanic or Latino	53	54	107
Race (NIH/OMB)			
Units: Subjects			
Asian	9	10	19
Black or African American	4	4	8
White	46	45	91
More than one race	1	0	1

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Participants will receive placebo for elezanumab via Intravenous (IV) infusion.	
Reporting group title	Elezanumab
Reporting group description: Participants will receive elezanumab 1800 mg via Intravenous (IV) infusion.	

Primary: National Institutes of Health Stroke Scale (NIHSS) Total Score During the Treatment Period

End point title	National Institutes of Health Stroke Scale (NIHSS) Total Score During the Treatment Period
End point description: The National Institutes of Health Stroke Scale (NIHSS) is a neurological examination used to quantitatively measure the severity of acute stroke by evaluating impact of cerebral infarction on level of consciousness, gaze, visual field, facial palsy, motor ability of arm and leg, limb ataxia, sensation, language, dysarthria, and extinction/inattention. Domains are scored on a scale of 0 to 2, 0 to 3, or 0 to 4, for a total range of 0 -42 points with higher scores indicating impairment.	
End point type	Primary
End point timeframe: Day 1 through Week 52	

End point values	Placebo	Elezanumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60	59		
Units: Area under the curve (AUC)				
number (confidence interval 95%)	3.83 (2.642 to 5.024)	3.13 (1.938 to 4.317)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: AUC analyses based on trapezoidal rule using contrast derived from MMRM with stratification factors, treatment, visit, and a treatment by visit interaction included in the model. Posterior probability that the difference in AUC exceeds 0.6 = 0.557	
Comparison groups	Elezanumab v Placebo

Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	other ^[1]
Parameter estimate	Area under the curve (AUC)
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.764
upper limit	2.175

Notes:

[1] - A statistical test was not performed.

Secondary: Responder Status based on Modified Rankin Scale (mRS)

End point title	Responder Status based on Modified Rankin Scale (mRS)
End point description:	
The mRS is used to assess participant's disability and functional dependence. It is a 6-point scale ranging from 0 (no symptoms) to 5 (severe disability), with additional rating of 6 if the participant is deceased.	
End point type	Secondary
End point timeframe:	
Week 52	

End point values	Placebo	Elezanumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46 ^[2]	38 ^[3]		
Units: participants	28	29		

Notes:

[2] - N indicates the number of subjects with non-missing values at each time point.

[3] - N indicates the number of subjects with non-missing values at each time point.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Point estimate for responder rate (defined as having an mRS score of 0, 1, or 2), odds ratio and 95% confidence intervals based on a generalized linear mixed model (GLMM).	
Comparison groups	Placebo v Elezanumab
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	other ^[4]
Parameter estimate	Odds Ratio of LS Means
Point estimate	1.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	4.24

Notes:

[4] - A statistical test was not performed.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality and adverse event tables include events reported from the time of informed consent to the end of the study. The median time on follow-up was 608.5 and 607 days for Placebo and Elezanumab 1800 mg, respectively.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	27.1

Reporting groups

Reporting group title	Elezanumab
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	Elezanumab	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 61 (29.51%)	23 / 60 (38.33%)	
number of deaths (all causes)	1	7	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps) MYELOPROLIFERATIVE NEOPLASM			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders HAEMATOMA			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEEP VEIN THROMBOSIS			
subjects affected / exposed	1 / 61 (1.64%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions NON-CARDIAC CHEST PAIN			

subjects affected / exposed	1 / 61 (1.64%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ASTHENIA			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUCOSAL DRYNESS			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
ACUTE PULMONARY OEDEMA			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY EMBOLISM			
subjects affected / exposed	1 / 61 (1.64%)	3 / 60 (5.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
DELIRIUM			
subjects affected / exposed	1 / 61 (1.64%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
TROPONIN INCREASED			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Injury, poisoning and procedural complications			
FEMORAL NECK FRACTURE			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HUMERUS FRACTURE			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FALL			
subjects affected / exposed	3 / 61 (4.92%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RIB FRACTURE			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULAR PSEUDOANEURYSM			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
GASTROINTESTINAL ARTERIOVENOUS MALFORMATION			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL SEPTAL DEFECT			

subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
SINUS NODE DYSFUNCTION			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CORONARY ARTERY DISEASE			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC VENTRICULAR THROMBOSIS			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL THROMBOSIS			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACUTE MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
ACUTE CORONARY SYNDROME			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
APHASIA			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

BASILAR ARTERY THROMBOSIS			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRAIN OEDEMA			
subjects affected / exposed	0 / 61 (0.00%)	3 / 60 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBRAL HAEMORRHAGE			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBRAL INFARCTION			
subjects affected / exposed	1 / 61 (1.64%)	2 / 60 (3.33%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	2 / 61 (3.28%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSARTHRIA			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FACIAL PARALYSIS			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMORRHAGE INTRACRANIAL			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMORRHAGIC TRANSFORMATION STROKE			

subjects affected / exposed	0 / 61 (0.00%)	2 / 60 (3.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEMIPARESIS			
subjects affected / exposed	1 / 61 (1.64%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LACUNAR INFARCTION			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PARTIAL SEIZURES			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PRESYNCOPE			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEIZURE			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SOMNOLENCE			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ISCHAEMIC STROKE			
subjects affected / exposed	0 / 61 (0.00%)	3 / 60 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Blood and lymphatic system disorders			
IRON DEFICIENCY ANAEMIA			

subjects affected / exposed	1 / 61 (1.64%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOCYTOPENIA			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANAEMIA			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
RETINAL HAEMORRHAGE			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
NEUTROPENIC COLITIS			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
CONSTIPATION			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
CHOLECYSTITIS			

subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATURIA			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
ARTHRITIS			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCULAR WEAKNESS			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
SEPTIC SHOCK			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PSEUDOMEMBRANOUS COLITIS			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA STAPHYLOCOCCAL			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

PNEUMONIA BACTERIAL			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA ASPIRATION			
subjects affected / exposed	1 / 61 (1.64%)	2 / 60 (3.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
PNEUMONIA			
subjects affected / exposed	0 / 61 (0.00%)	2 / 60 (3.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMOPHILUS INFECTION			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ESCHERICHIA BACTERAEMIA			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOCARDITIS BACTERIAL			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	1 / 61 (1.64%)	2 / 60 (3.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Metabolism and nutrition disorders			
DIABETES MELLITUS INADEQUATE CONTROL			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

HYPOKALAEMIA			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALNUTRITION			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (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	Elezanumab	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	49 / 61 (80.33%)	52 / 60 (86.67%)	
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	4 / 61 (6.56%)	10 / 60 (16.67%)	
occurrences (all)	4	13	
HYPOTENSION			
subjects affected / exposed	4 / 61 (6.56%)	2 / 60 (3.33%)	
occurrences (all)	4	2	
General disorders and administration site conditions			
FATIGUE			
subjects affected / exposed	1 / 61 (1.64%)	3 / 60 (5.00%)	
occurrences (all)	1	3	
OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 61 (1.64%)	6 / 60 (10.00%)	
occurrences (all)	1	6	
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 61 (0.00%)	4 / 60 (6.67%)	
occurrences (all)	0	4	
PYREXIA			
subjects affected / exposed	1 / 61 (1.64%)	3 / 60 (5.00%)	
occurrences (all)	1	3	
Psychiatric disorders			

INSOMNIA subjects affected / exposed occurrences (all)	10 / 61 (16.39%) 10	6 / 60 (10.00%) 6	
DEPRESSION subjects affected / exposed occurrences (all)	5 / 61 (8.20%) 5	3 / 60 (5.00%) 3	
DEPRESSED MOOD subjects affected / exposed occurrences (all)	4 / 61 (6.56%) 6	3 / 60 (5.00%) 4	
ANXIETY subjects affected / exposed occurrences (all)	6 / 61 (9.84%) 6	5 / 60 (8.33%) 6	
Injury, poisoning and procedural complications FALL subjects affected / exposed occurrences (all)	5 / 61 (8.20%) 7	11 / 60 (18.33%) 15	
SKIN LACERATION subjects affected / exposed occurrences (all)	4 / 61 (6.56%) 6	3 / 60 (5.00%) 3	
Cardiac disorders ATRIAL FIBRILLATION subjects affected / exposed occurrences (all)	6 / 61 (9.84%) 6	8 / 60 (13.33%) 10	
BRADYCARDIA subjects affected / exposed occurrences (all)	1 / 61 (1.64%) 1	4 / 60 (6.67%) 5	
Nervous system disorders DIZZINESS subjects affected / exposed occurrences (all)	6 / 61 (9.84%) 6	3 / 60 (5.00%) 4	
HAEMORRHAGIC TRANSFORMATION STROKE subjects affected / exposed occurrences (all)	7 / 61 (11.48%) 7	5 / 60 (8.33%) 5	
HEADACHE subjects affected / exposed occurrences (all)	7 / 61 (11.48%) 8	10 / 60 (16.67%) 11	

SYNCOPE subjects affected / exposed occurrences (all)	1 / 61 (1.64%) 1	5 / 60 (8.33%) 6	
Eye disorders DRY EYE subjects affected / exposed occurrences (all)	1 / 61 (1.64%) 1	3 / 60 (5.00%) 3	
Gastrointestinal disorders CONSTIPATION subjects affected / exposed occurrences (all) DIARRHOEA subjects affected / exposed occurrences (all) GASTROOESOPHAGEAL REFLUX DISEASE subjects affected / exposed occurrences (all) NAUSEA subjects affected / exposed occurrences (all)	11 / 61 (18.03%) 13 4 / 61 (6.56%) 4 0 / 61 (0.00%) 0 7 / 61 (11.48%) 7	13 / 60 (21.67%) 14 4 / 60 (6.67%) 4 3 / 60 (5.00%) 3 4 / 60 (6.67%) 4	
Skin and subcutaneous tissue disorders RASH subjects affected / exposed occurrences (all)	4 / 61 (6.56%) 4	4 / 60 (6.67%) 5	
Renal and urinary disorders ACUTE KIDNEY INJURY subjects affected / exposed occurrences (all) HAEMATURIA subjects affected / exposed occurrences (all) URINARY RETENTION subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0 5 / 61 (8.20%) 6 4 / 61 (6.56%) 4	3 / 60 (5.00%) 3 1 / 60 (1.67%) 1 1 / 60 (1.67%) 1	
Musculoskeletal and connective tissue disorders			

ARTHRALGIA subjects affected / exposed occurrences (all)	6 / 61 (9.84%) 6	8 / 60 (13.33%) 9	
BACK PAIN subjects affected / exposed occurrences (all)	3 / 61 (4.92%) 3	4 / 60 (6.67%) 4	
PAIN IN EXTREMITY subjects affected / exposed occurrences (all)	2 / 61 (3.28%) 2	4 / 60 (6.67%) 4	
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	5 / 61 (8.20%) 5	10 / 60 (16.67%) 10	
URINARY TRACT INFECTION subjects affected / exposed occurrences (all)	13 / 61 (21.31%) 16	11 / 60 (18.33%) 16	
Metabolism and nutrition disorders DIABETES MELLITUS subjects affected / exposed occurrences (all)	1 / 61 (1.64%) 1	5 / 60 (8.33%) 5	
HYPOKALAEMIA subjects affected / exposed occurrences (all)	5 / 61 (8.20%) 5	5 / 60 (8.33%) 5	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 June 2021	Version 2.0: The purpose of this version was to improve study execution, correct minor clerical errors and incorporate necessary protocol modifications due to the COVID-19 pandemic. The amendment increased target enrollment and number of sites, clarified monitoring time windows, and expanded Eligibility Criteria to increase upper age limit and allow inclusion of subjects who have undergone endovascular therapy (EVT).
25 March 2022	Version 3.0: The purpose of this amendment was to clarify screening period and window for administration of study drug, clarify eligibility for EVT subjects, simplify other eligibility criteria, update study design figure, update target proportion of sub-populations of subjects enrolled, correct infusion time, and address other minor typographical errors.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported