Clinical trial results:
A Multicentre, Randomized, Double-blind Study to Evaluate and Compare the Efficacy and Safety of 8-week Treatment with Azilsartan Medoxomil and Amlodipine Besylate Combined and Alone in Mild-to-moderate Essential Hypertensive Subjects

Summary

EudraCT number	2022-002539-79
Trial protocol	PL
Global end of trial date	19 July 2024

Results information

Result version number	v1
This version publication date	14 May 2026
First version publication date	14 May 2026
Summary attachment (see zip file)	CSR Synopsis (CT-L05-301_CSR synopsis_20Dec2024.pdf)

Trial information

Trial identification

Sponsor protocol code	CT-L05-301

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05385770
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Celltrion Inc.
Sponsor organisation address	23, Academy-ro, Yeonsu-gu, Incheon, Taiwan, 22014
Public contact	Clinical Planning 7 Team, Celltrion Inc., 1099633284 82-32-850-5000, sanghee.byun@celltrion.com
Scientific contact	Clinical Planning 7 Team , Celltrion Inc., 1099633284 82-32-850-4176, sanghee.byun@celltrion.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	20 December 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	19 July 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate antihypertensive efficacy of a combination of Azilsartan medoxomil and Amlodipine besylate, in mild-to-moderate essential hypertensive subjects not adequately controlled by Azilsartan medoxomil monotherapy or Amlodipine besylate monotherapy

Protection of trial subjects:

This study has been approved by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and has received a favorable opinion of the appropriate Ethics Committee, an independent organization that is responsible for making sure that the rights, safety and well-being of patients who take part in clinical research studies are protected. The approval by the by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and the favourable opinion of the appropriate Ethics Committee should not be thought of as an encouragement for you to take part in this study.
Even if you choose to take part in the study and sign the Informed consent forms, you are still free to withdraw from the study at any time without giving a reason. If you withdraw from the study, we will ask you to return for a post-study assessment to check your health. You may withdraw from the study at any time at your own request or may be withdrawn at any time at the discretion of the study doctor for safety, behavioral, or administrative reasons. Additional reasons for discontinuation can include, but are not limited to: death, adverse events, lack of efficacy of study treatment, pregnancy, sponsor determination, cardiac changes (QTcF), or your study doctor not being able to get in touch with you.
The regulatory authorities supervising clinical trials and the responsible Ethics Committee (which reviews study safety procedures and reviews for ethics to ensure patients' rights are not violated) also have the right to discontinue the study at any time, which will mean that you will be withdrawn from the study.
Your identity, your personal health data and samples will be kept confidential. Without your consent, your personal data and samples cannot be used or shared with others. This is why you will not be able to take part in the study if you do not give your consent to use your personal data and samples.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 May 2022
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: 408
Country: Number of subjects enrolled	Korea, Republic of: 436
Country: Number of subjects enrolled	Taiwan: 46
Worldwide total number of subjects	890
EEA total number of subjects	408

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)	483
From 65 to 84 years	407
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This was a multicentre, randomized, doubleblind Phase 3 study in subjects with mildtomoderate essential hypertension whose blood pressure was not adequately controlled on azilsartan medoxomil (40 or 80 mg) or amlodipine besylate (5 or 10 mg) monotherapy. Recruitment was conducted at participating clinical trial sites in Korea, Taiwan and Poland

Pre-assignment

Screening details:

Potential subjects attended an onsite screening visit to assess eligibility against predefined inclusion/exclusion criteria and to obtain written informed consent. A screening period of up to approximately 2 weeks was used, including washout of prior antihypertensive medications other than AZM or AML when applicable (up to 2 weeks).

Period 1

Period 1 title	double-blind treatment 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	AZM/AML 40/10 mg

Arm description:

AZM 40 mg non responder group

Arm type	Experimental
Investigational medicinal product name	AZM/AML 40/10 mg
Investigational medicinal product code	AZM/AML
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral, Once a day

Arm title	AZM/AML 40/5 mg

Arm description:

AZM 40 mg non responder group

Arm type	Experimental
Investigational medicinal product name	AZM/AML 40/5 mg
Investigational medicinal product code	AZM/AML
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral, Once a day

Arm title	AZM 40 mg

Arm description:

AZM 40 mg non responder group

Arm type	Experimental

Investigational medicinal product name	AZM 40 mg
Investigational medicinal product code	AZM
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Oral, Once a day

Arm title	AZM/AML 80/10 mg

Arm description:
AZM 80 mg non-responder group

Arm type	Experimental
Investigational medicinal product name	AZM/AML 80/10 mg
Investigational medicinal product code	AZM/AML
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Oral, Once a day

Arm title	AZM/AML 80/5 mg

Arm description:
AZM 80 mg non-responder group

Arm type	Experimental
Investigational medicinal product name	AZM/AML 80/5 mg
Investigational medicinal product code	AZM/AML
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Oral, Once a day

Arm title	AZM 80 mg

Arm description:
AZM 80 mg non-responder group

Arm type	Experimental
Investigational medicinal product name	AZM 80 mg
Investigational medicinal product code	AZM
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Oral, Once a day

Arm title	AZM/AML 80/5 mg

Arm description:
AML 5 mg non-responder group

Arm type	Experimental

Investigational medicinal product name	AZM/AML 80/5 mg
Investigational medicinal product code	AZM/AML
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Oral, Once a day

Arm title	AZM/AML 40/5 mg

Arm description:
AML 5 mg non-responder group

Arm type	Experimental
Investigational medicinal product name	AZM/AML 40/5 mg
Investigational medicinal product code	AZM/AML
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Oral, Once a day

Arm title	AML 5 mg

Arm description:
AML 5 mg non-responder group

Arm type	Experimental
Investigational medicinal product name	AML 5 mg
Investigational medicinal product code	AML
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Oral, Once a day

Arm title	AZM/AML 80/10 mg

Arm description:
AML 10 mg non-responder group

Arm type	Experimental
Investigational medicinal product name	AZM/AML 80/10 mg
Investigational medicinal product code	AZM/AML
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Oral, Once a day

Arm title	AZM/AML 40/10 mg

Arm description:
AM 10 mg non-responder group

Arm type	Experimental

Investigational medicinal product name	AZM/AML 40/10 mg
Investigational medicinal product code	AZM/AML
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral, Once a day

Arm title	AML 10 mg

Arm description:

AML 10 mg non-responder group

Arm type	Experimental
Investigational medicinal product name	AML 10 mg
Investigational medicinal product code	AML
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral, Once a day

Number of subjects in period 1	AZM/AML 40/10 mg	AZM/AML 40/5 mg	AZM 40 mg
Started	75	75	75
Completed	73	74	74
Not completed	2	1	1
Not Dosed	2	-	-
Not Evaluable Data for Primary efficacy	-	1	1

Number of subjects in period 1	AZM/AML 80/10 mg	AZM/AML 80/5 mg	AZM 80 mg
Started	69	70	72
Completed	66	68	68
Not completed	3	2	4
Not Dosed	2	1	2
Not Evaluable Data for Primary efficacy	1	1	2

Number of subjects in period 1	AZM/AML 80/5 mg	AZM/AML 40/5 mg	AML 5 mg
Started	80	80	81
Completed	79	78	79
Not completed	1	2	2
Not Dosed	1	1	1
Not Evaluable Data for Primary efficacy	-	1	1

Number of subjects in period 1	AZM/AML 80/10 mg	AZM/AML 40/10 mg	AML 10 mg
Started	72	70	71

Completed	70	68	71
Not completed	2	2	0
Not Dosed	1	-	-
Not Evaluable Data for Primary efficacy	1	2	-

Baseline characteristics

Reporting groups	
Reporting group title	AZM/AML 40/10 mg
Reporting group description: AZM 40 mg non responder group	
Reporting group title	AZM/AML 40/5 mg
Reporting group description: AZM 40 mg non responder group	
Reporting group title	AZM 40 mg
Reporting group description: AZM 40 mg non responder group	
Reporting group title	AZM/AML 80/10 mg
Reporting group description: AZM 80 mg non-responder group	
Reporting group title	AZM/AML 80/5 mg
Reporting group description: AZM 80 mg non-responder group	
Reporting group title	AZM 80 mg
Reporting group description: AZM 80 mg non-responder group	
Reporting group title	AZM/AML 80/5 mg
Reporting group description: AML 5 mg non-responder group	
Reporting group title	AZM/AML 40/5 mg
Reporting group description: AML 5 mg non-responder group	
Reporting group title	AML 5 mg
Reporting group description: AML 5 mg non-responder group	
Reporting group title	AZM/AML 80/10 mg
Reporting group description: AML 10 mg non-responder group	
Reporting group title	AZM/AML 40/10 mg
Reporting group description: AM 10 mg non-responder group	
Reporting group title	AML 10 mg
Reporting group description: AML 10 mg non-responder group	

Reporting group values	AZM/AML 40/10 mg	AZM/AML 40/5 mg	AZM 40 mg
Number of subjects	75	75	75
Age categorical Units: Subjects			
Adults (18-64 years)	45	47	39
Adults (≥65 years)	30	28	36
Gender categorical Units: Subjects			
Female	33	32	33

Male	42	43	42

Reporting group values	AZM/AML 80/10 mg	AZM/AML 80/5 mg	AZM 80 mg
Number of subjects	69	70	72
Age categorical Units: Subjects			
Adults (18-64 years)	34	34	39
Adults (≥65 years)	35	36	33
Gender categorical Units: Subjects			
Female	27	27	26
Male	42	43	46

Reporting group values	AZM/AML 80/5 mg	AZM/AML 40/5 mg	AML 5 mg
Number of subjects	80	80	81
Age categorical Units: Subjects			
Adults (18-64 years)	55	42	49
Adults (≥65 years)	25	38	32
Gender categorical Units: Subjects			
Female	34	26	26
Male	46	54	55

Reporting group values	AZM/AML 80/10 mg	AZM/AML 40/10 mg	AML 10 mg
Number of subjects	72	70	71
Age categorical Units: Subjects			
Adults (18-64 years)	35	38	26
Adults (≥65 years)	37	32	45
Gender categorical Units: Subjects			
Female	23	31	31
Male	49	39	40

Reporting group values	Total		
Number of subjects	890		
Age categorical Units: Subjects			
Adults (18-64 years)	483		
Adults (≥65 years)	407		
Gender categorical Units: Subjects			
Female	349		
Male	541		

Subject analysis sets

Subject analysis set title	Full Analysis Set
Subject analysis set type	Full analysis

Subject analysis set description:

Overall, the majority of subjects were male (529/868, 60.9%) and Asian (477/868, 55.0%). Mean age was 60.4 years and most subjects were ≥45 years of age (772/868, 88.9%, including 398 subjects [45.9%] ≥65 years of age).

Subject analysis set title	Intent-to-Treat Set
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All subjects randomized were included in the ITT Set. Intent-to-Treat Set subjects were analyzed according to their randomized treatment.

Reporting group values	Full Analysis Set	Intent-to-Treat Set	
Number of subjects	868	890	
Age categorical Units: Subjects			
Adults (18-64 years)	470	483	
Adults (≥65 years)	398	407	
Gender categorical Units: Subjects			
Female	339	349	
Male	529	541	

End points

End points reporting groups

Reporting group title	AZM/AML 40/10 mg
Reporting group description: AZM 40 mg non responder group	
Reporting group title	AZM/AML 40/5 mg
Reporting group description: AZM 40 mg non responder group	
Reporting group title	AZM 40 mg
Reporting group description: AZM 40 mg non responder group	
Reporting group title	AZM/AML 80/10 mg
Reporting group description: AZM 80 mg non-responder group	
Reporting group title	AZM/AML 80/5 mg
Reporting group description: AZM 80 mg non-responder group	
Reporting group title	AZM 80 mg
Reporting group description: AZM 80 mg non-responder group	
Reporting group title	AZM/AML 80/5 mg
Reporting group description: AML 5 mg non-responder group	
Reporting group title	AZM/AML 40/5 mg
Reporting group description: AML 5 mg non-responder group	
Reporting group title	AML 5 mg
Reporting group description: AML 5 mg non-responder group	
Reporting group title	AZM/AML 80/10 mg
Reporting group description: AML 10 mg non-responder group	
Reporting group title	AZM/AML 40/10 mg
Reporting group description: AM 10 mg non-responder group	
Reporting group title	AML 10 mg
Reporting group description: AML 10 mg non-responder group	
Subject analysis set title	Full Analysis Set
Subject analysis set type	Full analysis
Subject analysis set description: Overall, the majority of subjects were male (529/868, 60.9%) and Asian (477/868, 55.0%). Mean age was 60.4 years and most subjects were ≥45 years of age (772/868, 88.9%, including 398 subjects [45.9%] ≥65 years of age).	
Subject analysis set title	Intent-to-Treat Set
Subject analysis set type	Intention-to-treat
Subject analysis set description: All subjects randomized were included in the ITT Set. Intent-to-Treat Set subjects were analyzed according to their randomized treatment.	

Primary: change from baseline to Week 8 in msitSBP

End point title	change from baseline to Week 8 in msitSBP

End point description:

End point type	Primary

End point timeframe:

The primary outcome of interest was the change from baseline in msitSBP after 8 weeks of treatment.

End point values	AZM/AML 40/10 mg	AZM/AML 40/5 mg	AZM 40 mg	AZM/AML 80/10 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	74	74	66
Units: mmHg				
least squares mean (standard deviation)	-16.844 (± 1.6627)	-13.824 (± 1.6563)	-9.082 (± 1.6514)	-18.197 (± 1.8951)

End point values	AZM/AML 80/5 mg	AZM 80 mg	AZM/AML 80/5 mg	AZM/AML 40/5 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	68	68	79	78
Units: mmHg				
least squares mean (standard deviation)	-16.995 (± 1.7530)	-9.205 (± 1.8669)	-14.580 (± 1.4093)	-14.325 (± 1.3263)

End point values	AML 5 mg	AZM/AML 80/10 mg	AZM/AML 40/10 mg	AML 10 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	79	70	68	71
Units: mmHg				
least squares mean (standard deviation)	-7.222 (± 1.4093)	-13.306 (± 1.5232)	-15.587 (± 1.5840)	-6.657 (± 1.5124)

Statistical analyses

Statistical analysis title	the change from baseline in msitSBP after 8 weeks

Statistical analysis description:

the change from baseline in msitSBP after 8 weeks of treatment.

Comparison groups	AZM 40 mg v AZM 80 mg v AML 5 mg v AML 10 mg

Number of subjects included in analysis	292
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Confidence interval	
sides	2-sided
Variability estimate	Standard deviation

Adverse events

Adverse events information	
Timeframe for reporting adverse events: during the treatment period after first administration of the investigational product (IP)	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	27

Reporting groups	
Reporting group title	AZM 40 mg non-responder group
Reporting group description: -	
Reporting group title	AZM 80 mg non-responder group
Reporting group description: -	
Reporting group title	AML 5 mg non responder group
Reporting group description: -	
Reporting group title	AML 10 mg non-responder group
Reporting group description: -	

Serious adverse events	AZM 40 mg non-responder group	AZM 80 mg non-responder group	AML 5 mg non responder group
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 223 (0.45%)	0 / 206 (0.00%)	2 / 238 (0.84%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
subjects affected / exposed	1 / 223 (0.45%)	0 / 206 (0.00%)	0 / 238 (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
Small cell lung cancer metastatic			
subjects affected / exposed	0 / 223 (0.00%)	0 / 206 (0.00%)	1 / 238 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 223 (0.00%)	0 / 206 (0.00%)	1 / 238 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Angina pectoris			
subjects affected / exposed	0 / 223 (0.00%)	0 / 206 (0.00%)	0 / 238 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Haemothorax			
subjects affected / exposed	0 / 223 (0.00%)	0 / 206 (0.00%)	0 / 238 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 223 (0.00%)	0 / 206 (0.00%)	0 / 238 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	0 / 223 (0.00%)	0 / 206 (0.00%)	0 / 238 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	0 / 223 (0.00%)	0 / 206 (0.00%)	0 / 238 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 223 (0.00%)	0 / 206 (0.00%)	0 / 238 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	AML 10 mg non-responder group		
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 212 (2.83%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			

subjects affected / exposed	0 / 212 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small cell lung cancer metastatic				
subjects affected / exposed	0 / 212 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Acute myocardial infarction				
subjects affected / exposed	0 / 212 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Angina pectoris				
subjects affected / exposed	1 / 212 (0.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Haemothorax				
subjects affected / exposed	1 / 212 (0.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Cellulitis				
subjects affected / exposed	1 / 212 (0.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abscess limb				
subjects affected / exposed	1 / 212 (0.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diverticulitis intestinal haemorrhagic				
subjects affected / exposed	1 / 212 (0.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Pneumonia			
subjects affected / exposed	1 / 212 (0.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	AZM 40 mg non-responder group	AZM 80 mg non-responder group	AML 5 mg non responder group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 223 (2.69%)	5 / 206 (2.43%)	5 / 238 (2.10%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 223 (0.00%)	0 / 206 (0.00%)	5 / 238 (2.10%)
occurrences (all)	0	0	5
Metabolism and nutrition disorders			
Hypertriglyceridaemia			
subjects affected / exposed	6 / 223 (2.69%)	3 / 206 (1.46%)	0 / 238 (0.00%)
occurrences (all)	6	3	0
Hyperuricaemia			
subjects affected / exposed	0 / 223 (0.00%)	2 / 206 (0.97%)	0 / 238 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	AML 10 mg non-responder group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 212 (0.00%)		
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 212 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Hypertriglyceridaemia			
subjects affected / exposed	0 / 212 (0.00%)		
occurrences (all)	0		
Hyperuricaemia			
subjects affected / exposed	0 / 212 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 August 2021	The first version
04 November 2021	As per MFDS regulatory requirements Add discontinuation criteria Unify the term and clarify the expression, etc.
25 March 2022	As per TFDA regulatory requirements Changes in clinical laboratory analytes Typo correction, etc.
27 April 2022	As per TFDA regulatory requirements Update prohibited therapy and management after study completion for clarification. Update MedDRA version Typo correction, etc.
07 June 2022	Appendix 5 update (To specify COVID-19 confirmed subject participation guideline) Discrepancy, Typo correction, etc.
27 September 2022	Update of the inclusion/exclusion criteria Clarification of additional analyses including subgroup analyses if necessary Correction of discrepancy, typo and etc.
28 July 2023	Update of overall study design and plan description Update of the exclusion criteria Update of unnecessary description and additional clarification of Study procedures and assessments Update of the information of drug manufacturer Update to clarify the analysis populations of FAS Correction of discrepancy, typo etc.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported