



Clinical trial results:

A 4-part Phase 1/2 Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of M254 in Healthy Volunteers and in Patients with Immune Thrombocytopenic Purpura Summary

EudraCT number	2018-003534-32
Trial protocol	NL BE HU PL ES IT
Global end of trial date	08 June 2021

Results information

Result version number	v1 (current)
This version publication date	11 June 2022
First version publication date	11 June 2022

Trial information

Trial identification

Sponsor protocol code	MOM-M254-001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03866577
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Momenta Pharmaceuticals, Inc.
Sponsor organisation address	301 Binney Street, Cambridge, United States, 02142
Public contact	Clinical Registry Group, Momenta Pharmaceuticals, Inc., ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Momenta Pharmaceuticals, Inc., ClinicalTrialsEU@its.jnj.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	08 June 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	08 June 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was: to assess the safety and tolerability of a single ascending dose of intravenous (IV) administration of M254 in healthy subjects (Part A); to assess the safety and tolerability of a single IV administration of M254 in immunethrombocytopenia (ITP) subjects compared to 1000 milligrams/kilogram (mg/kg) IV immunoglobulin (IVIg) (Part B); to assess the safety of a single IV administration of M254 compared to 1000 mg/kg of IVIg and characterize the pharmacodynamics (PD) of single IV administration of M254 compared to 1000 mg/kg IVIg (Part C); to assess the safety and tolerability of repeated IV administration of M254 in ITP subjects (Part D).

Protection of trial subjects:

The study was conducted in accordance with the principles of the Declaration of Helsinki in place at the time of study conduct. The study was conducted in compliance with the International Council for Harmonisation (ICH) E6 Guideline for Good Clinical Practice (GCP) (European Medicines Agency [EMA]/Committee for Medicinal Products for Human Use [CHMP]/ICH/135/1995), and compliant with the European Union Clinical Trial Directive (EU CTD): Directive 2001/20/EC.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 January 2019
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	Belgium: 1
Country: Number of subjects enrolled	Spain: 2
Country: Number of subjects enrolled	Hungary: 4
Country: Number of subjects enrolled	Italy: 1
Country: Number of subjects enrolled	Netherlands: 27
Country: Number of subjects enrolled	Poland: 15
Worldwide total number of subjects	50
EEA total number of subjects	50

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	45
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Out of 50 enrolled subjects, 46 subjects completed the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
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Arm title	Part A: Placebo
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Arm description:

Subjects received a single intravenous (IV) infusion of matching placebo on Day 1.

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

Dosage and administration details:

A single dose of matching placebo was administered on Day 1.

Arm title	Part A: M254 3 milligrams/kilogram (mg/kg)
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Arm description:

Subjects received a single IV infusion of M254 3 mg/kg on Day 1.

Arm type	Experimental
Investigational medicinal product name	M254
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

A single dose of M254 3 mg/kg was administered on Day 1.

Arm title	Part A: M254 10 mg/kg
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Arm description:

Subjects received a single IV infusion of M254 10 mg/kg on Day 1.

Arm type	Experimental
Investigational medicinal product name	M254
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

A single dose of M254 10 mg/kg was administered on Day 1.

Arm title	Part A: M254 30 mg/kg
Arm description: Subjects received a single IV infusion of M254 30 mg/kg on Day 1.	
Arm type	Experimental
Investigational medicinal product name	M254
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: A single dose of M254 30 mg/kg was administered on Day 1.	
Arm title	Part A: M254 60 mg/kg
Arm description: Subjects received a single IV infusion of M254 60 mg/kg on Day 1.	
Arm type	Experimental
Investigational medicinal product name	M254
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: A single dose of M254 60 mg/kg was administered on Day 1.	
Arm title	Part A: M254 120 mg/kg
Arm description: Subjects received a single IV infusion of M254 120 mg/kg on Day 1.	
Arm type	Experimental
Investigational medicinal product name	M254
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: A single dose of M254 120 mg/kg was administered on Day 1.	
Arm title	Part A: M254 250 mg/kg
Arm description: Subjects received a single IV infusion of M254 250 mg/kg on Day 1.	
Arm type	Experimental
Investigational medicinal product name	M254
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: A single dose of M254 250 mg/kg was administered on Day 1.	
Arm title	Part B: M254 20 mg/kg and IV immunoglobulin (IVIg) 1000 mg/kg
Arm description: Subjects with immune thrombocytopenia purpura (ITP) received a single IV infusion of M254 20 mg/kg on Day 1 followed by a single IV infusion of IVIg 1000 mg/kg on Day 29.	
Arm type	Experimental

Investigational medicinal product name	IVIg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
A single dose of IVIg 1000 mg/kg was administered on Day 29.	
Investigational medicinal product name	M254
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
A single dose of M254 20 mg/kg was administered on Day 1.	
Arm title	Part B: M254 60 mg/kg and IVIg 1000 mg/kg
Arm description:	
Subjects with ITP received a single IV infusion of M254 60 mg/kg on Day 1 followed by a single IV infusion of IVIg 1000 mg/kg on Day 29.	
Arm type	Experimental
Investigational medicinal product name	IVIg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
A single dose of IVIg 1000 mg/kg was administered on Day 29.	
Investigational medicinal product name	M254
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
A single dose of M254 60 mg/kg was administered on Day 1.	
Arm title	Part B: M254 120 mg/kg and IVIg 1000 mg/kg
Arm description:	
Subjects with ITP received a single IV infusion of M254 120 mg/kg on Day 1 followed by a single IV infusion of IVIg 1000 mg/kg on Day 29.	
Arm type	Experimental
Investigational medicinal product name	IVIg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
A single dose of IVIg 1000 mg/kg was administered on Day 29.	
Investigational medicinal product name	M254
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
A single dose of M254 120 mg/kg was administered on Day 1.	

Arm title	Part B: M254 250 mg/kg and IVIg 1000 mg/kg
Arm description: Subjects with ITP received a single IV infusion of M254 250 mg/kg on Day 1 followed by a single IV infusion of IVIg 1000 mg/kg on Day 29.	
Arm type	Experimental
Investigational medicinal product name	IVIg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: A single dose of IVIg 1000 mg/kg was administered on Day 29.	
Investigational medicinal product name	M254
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: A single dose of M254 250 mg/kg was administered on Day 1.	
Arm title	Part C: M254 120 mg/kg and IVIg 1000 mg/kg
Arm description: Subjects with ITP received a single IV infusion of M254 120 mg/kg on Day 1 followed by a single IV infusion of IVIg 1000 mg/kg on Day 29.	
Arm type	Experimental
Investigational medicinal product name	M254
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: A single dose of M254 120 mg/kg was administered on Day 1.	
Investigational medicinal product name	IVIg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: A single dose of IVIg 1000 mg/kg was administered on Day 29.	
Arm title	Part C: IVIg 1000 mg/kg and M254 120 mg/kg
Arm description: Subjects with ITP received a single IV infusion of IVIg 1000 mg/kg on Day 1 followed by a single IV infusion of M254 120 mg/kg on Day 29.	
Arm type	Experimental
Investigational medicinal product name	M254
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: A single dose of M254 120 mg/kg was administered on Day 29.	

Investigational medicinal product name	IVIg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

A single dose of IVIg 1000 mg/kg was administered on Day 1.

Number of subjects in period 1	Part A: Placebo	Part A: M254 3 milligrams/kilogram (mg/kg)	Part A: M254 10 mg/kg
Started	7	3	3
Completed	7	3	3
Not completed	0	0	0
Consent withdrawn by subject	-	-	-
Not qualified for IVIg infusion	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part A: M254 30 mg/kg	Part A: M254 60 mg/kg	Part A: M254 120 mg/kg
Started	3	3	3
Completed	3	3	3
Not completed	0	0	0
Consent withdrawn by subject	-	-	-
Not qualified for IVIg infusion	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part A: M254 250 mg/kg	Part B: M254 20 mg/kg and IV immunoglobulin (IVIg) 1000 mg/kg	Part B: M254 60 mg/kg and IVIg 1000 mg/kg
Started	3	2	5
Completed	3	2	4
Not completed	0	0	1
Consent withdrawn by subject	-	-	1
Not qualified for IVIg infusion	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part B: M254 120 mg/kg and IVIg 1000 mg/kg	Part B: M254 250 mg/kg and IVIg 1000 mg/kg	Part C: M254 120 mg/kg and IVIg 1000 mg/kg
Started	5	2	6
Completed	3	2	5
Not completed	2	0	1
Consent withdrawn by subject	1	-	-
Not qualified for IVIg infusion	1	-	-
Protocol deviation	-	-	1

Number of subjects in period 1	Part C: IVIg 1000 mg/kg and M254 120 mg/kg
Started	5
Completed	5
Not completed	0
Consent withdrawn by subject	-
Not qualified for IVIg infusion	-
Protocol deviation	-

Baseline characteristics

Reporting groups

Reporting group title	Part A: Placebo
Reporting group description: Subjects received a single intravenous (IV) infusion of matching placebo on Day 1.	
Reporting group title	Part A: M254 3 milligrams/kilogram (mg/kg)
Reporting group description: Subjects received a single IV infusion of M254 3 mg/kg on Day 1.	
Reporting group title	Part A: M254 10 mg/kg
Reporting group description: Subjects received a single IV infusion of M254 10 mg/kg on Day 1.	
Reporting group title	Part A: M254 30 mg/kg
Reporting group description: Subjects received a single IV infusion of M254 30 mg/kg on Day 1.	
Reporting group title	Part A: M254 60 mg/kg
Reporting group description: Subjects received a single IV infusion of M254 60 mg/kg on Day 1.	
Reporting group title	Part A: M254 120 mg/kg
Reporting group description: Subjects received a single IV infusion of M254 120 mg/kg on Day 1.	
Reporting group title	Part A: M254 250 mg/kg
Reporting group description: Subjects received a single IV infusion of M254 250 mg/kg on Day 1.	
Reporting group title	Part B: M254 20 mg/kg and IV immunoglobulin (IVIg) 1000 mg/kg
Reporting group description: Subjects with immune thrombocytopenia purpura (ITP) received a single IV infusion of M254 20 mg/kg on Day 1 followed by a single IV infusion of IVIg 1000 mg/kg on Day 29.	
Reporting group title	Part B: M254 60 mg/kg and IVIg 1000 mg/kg
Reporting group description: Subjects with ITP received a single IV infusion of M254 60 mg/kg on Day 1 followed by a single IV infusion of IVIg 1000 mg/kg on Day 29.	
Reporting group title	Part B: M254 120 mg/kg and IVIg 1000 mg/kg
Reporting group description: Subjects with ITP received a single IV infusion of M254 120 mg/kg on Day 1 followed by a single IV infusion of IVIg 1000 mg/kg on Day 29.	
Reporting group title	Part B: M254 250 mg/kg and IVIg 1000 mg/kg
Reporting group description: Subjects with ITP received a single IV infusion of M254 250 mg/kg on Day 1 followed by a single IV infusion of IVIg 1000 mg/kg on Day 29.	
Reporting group title	Part C: M254 120 mg/kg and IVIg 1000 mg/kg
Reporting group description: Subjects with ITP received a single IV infusion of M254 120 mg/kg on Day 1 followed by a single IV infusion of IVIg 1000 mg/kg on Day 29.	
Reporting group title	Part C: IVIg 1000 mg/kg and M254 120 mg/kg
Reporting group description: Subjects with ITP received a single IV infusion of IVIg 1000 mg/kg on Day 1 followed by a single IV infusion of M254 120 mg/kg on Day 29.	

Reporting group values	Part A: Placebo	Part A: M254 3 milligrams/kilogram (mg/kg)	Part A: M254 10 mg/kg
Number of subjects	7	3	3
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	7	3	3
From 65 to 84 years	0	0	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	32.9	31.3	32
standard deviation	± 10.9	± 7.64	± 13.75
Title for Gender Units: subjects			
Female	4	1	2
Male	3	2	1

Reporting group values	Part A: M254 30 mg/kg	Part A: M254 60 mg/kg	Part A: M254 120 mg/kg
Number of subjects	3	3	3
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	3	3
From 65 to 84 years	0	0	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	27	29	32.7
standard deviation	± 1	± 7.81	± 15.53
Title for Gender Units: subjects			
Female	2	0	2
Male	1	3	1

Reporting group values	Part A: M254 250 mg/kg	Part B: M254 20 mg/kg and IV immunoglobulin (IVIg) 1000 mg/kg	Part B: M254 60 mg/kg and IVIg 1000 mg/kg
Number of subjects	3	2	5
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	2	5
From 65 to 84 years	0	0	0
85 years and over	0	0	0

Title for AgeContinuous Units: years arithmetic mean standard deviation	24.3 ± 4.51	44 ± 4.24	51.8 ± 11.45
Title for Gender Units: subjects			
Female	2	1	3
Male	1	1	2

Reporting group values	Part B: M254 120 mg/kg and IVIg 1000 mg/kg	Part B: M254 250 mg/kg and IVIg 1000 mg/kg	Part C: M254 120 mg/kg and IVIg 1000 mg/kg
Number of subjects	5	2	6
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	2	3
From 65 to 84 years	0	0	3
85 years and over	0	0	0
Title for AgeContinuous Units: years arithmetic mean standard deviation	44 ± 12.94	54.5 ± 13.44	58 ± 14.48
Title for Gender Units: subjects			
Female	4	1	2
Male	1	1	4

Reporting group values	Part C: IVIg 1000 mg/kg and M254 120 mg/kg	Total	
Number of subjects	5	50	
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	3	45	
From 65 to 84 years	2	5	
85 years and over	0	0	
Title for AgeContinuous Units: years arithmetic mean standard deviation	60 ± 12.63	-	
Title for Gender Units: subjects			
Female	2	26	
Male	3	24	

End points

End points reporting groups

Reporting group title	Part A: Placebo
Reporting group description: Subjects received a single intravenous (IV) infusion of matching placebo on Day 1.	
Reporting group title	Part A: M254 3 milligrams/kilogram (mg/kg)
Reporting group description: Subjects received a single IV infusion of M254 3 mg/kg on Day 1.	
Reporting group title	Part A: M254 10 mg/kg
Reporting group description: Subjects received a single IV infusion of M254 10 mg/kg on Day 1.	
Reporting group title	Part A: M254 30 mg/kg
Reporting group description: Subjects received a single IV infusion of M254 30 mg/kg on Day 1.	
Reporting group title	Part A: M254 60 mg/kg
Reporting group description: Subjects received a single IV infusion of M254 60 mg/kg on Day 1.	
Reporting group title	Part A: M254 120 mg/kg
Reporting group description: Subjects received a single IV infusion of M254 120 mg/kg on Day 1.	
Reporting group title	Part A: M254 250 mg/kg
Reporting group description: Subjects received a single IV infusion of M254 250 mg/kg on Day 1.	
Reporting group title	Part B: M254 20 mg/kg and IV immunoglobulin (IVIg) 1000 mg/kg
Reporting group description: Subjects with immune thrombocytopenia purpura (ITP) received a single IV infusion of M254 20 mg/kg on Day 1 followed by a single IV infusion of IVIg 1000 mg/kg on Day 29.	
Reporting group title	Part B: M254 60 mg/kg and IVIg 1000 mg/kg
Reporting group description: Subjects with ITP received a single IV infusion of M254 60 mg/kg on Day 1 followed by a single IV infusion of IVIg 1000 mg/kg on Day 29.	
Reporting group title	Part B: M254 120 mg/kg and IVIg 1000 mg/kg
Reporting group description: Subjects with ITP received a single IV infusion of M254 120 mg/kg on Day 1 followed by a single IV infusion of IVIg 1000 mg/kg on Day 29.	
Reporting group title	Part B: M254 250 mg/kg and IVIg 1000 mg/kg
Reporting group description: Subjects with ITP received a single IV infusion of M254 250 mg/kg on Day 1 followed by a single IV infusion of IVIg 1000 mg/kg on Day 29.	
Reporting group title	Part C: M254 120 mg/kg and IVIg 1000 mg/kg
Reporting group description: Subjects with ITP received a single IV infusion of M254 120 mg/kg on Day 1 followed by a single IV infusion of IVIg 1000 mg/kg on Day 29.	
Reporting group title	Part C: IVIg 1000 mg/kg and M254 120 mg/kg
Reporting group description: Subjects with ITP received a single IV infusion of IVIg 1000 mg/kg on Day 1 followed by a single IV infusion of M254 120 mg/kg on Day 29.	
Subject analysis set title	Part B: M254 20 mg/kg - M254 period
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects with immune thrombocytopenia purpura (ITP) received a single intravenous (IV) infusion of	

M254 20 milligrams/kilogram (mg/kg) on Day 1.

Subject analysis set title	Part B: M254 20 mg/kg - IVIg period
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with ITP received a single IV infusion of IV immunoglobulin (IVIg) 1000 mg/kg on Day 29.

Subject analysis set title	Part B: M254 60 mg/kg - M254 period
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with ITP received a single IV infusion of M254 60 mg/kg on Day 1.

Subject analysis set title	Part B: M254 60 mg/kg - IVIg period
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with ITP received a single IV infusion of IVIg 1000 mg/kg on Day 29.

Subject analysis set title	Part B: M254 120 mg/kg - M254 period
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with ITP received a single IV infusion of M254 120 mg/kg on Day 1.

Subject analysis set title	Part B: M254 120 mg/kg - IVIg period
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with ITP received a single IV infusion of IVIg 1000 mg/kg on Day 29.

Subject analysis set title	Part B: M254 250 mg/kg - M254 period
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with ITP received a single IV infusion of M254 250 mg/kg on Day 1.

Subject analysis set title	Part B: M254 250 mg/kg - IVIg period
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with ITP received a single IV infusion of IVIg 1000 mg/kg on Day 29.

Subject analysis set title	Part C: M254 120 mg/kg and IVIg 1000 mg/kg - M254 period
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with ITP received a single IV infusion of M254 120 mg/kg on Day 1.

Subject analysis set title	Part C: M254 120 mg/kg and IVIg 1000 mg/kg - IVIg period
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with ITP received a single IV infusion of IVIg 1000 mg/kg on Day 29.

Subject analysis set title	Part C: IVIg 1000 mg/kg and M254 120 mg/kg - IVIg period
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with ITP received a single IV infusion of IVIg 1000 mg/kg on Day 1.

Subject analysis set title	Part C: IVIg 1000 mg/kg and M254 120 mg/kg - M254 period
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects with ITP received a single IV infusion of M254 120 mg/kg on Day 29.

Subject analysis set title	Part C: M254 120 mg/kg
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects with ITP received a single IV infusion of M254 120 mg/kg on Day 1 or Day 29.

Subject analysis set title	Part C: IVIg 1000 mg/kg
Subject analysis set type	Full analysis

Primary: Parts A, B, and C: Number of Subjects with Adverse Events (AE) by Severity as a Measure of Safety and Tolerability

End point title	Parts A, B, and C: Number of Subjects with Adverse Events (AE) by Severity as a Measure of Safety and Tolerability ^{[1][2]}
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End point description:

An AE is any untoward medical event that occurs in a subject administered an investigational product, and it does not necessarily indicate only events with clear causal relationship with the relevant investigational product. Safety analysis set included all subjects who received at least 1 dose of M254 or intravenous immunoglobulin (IVIg) or placebo. Severity will be graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) version 5.0. Severity scale ranges from Grade 1 (Mild) to Grade 5 (Death). Grade 1= Mild, Grade 2= Moderate, Grade 3= Severe, Grade 4= Life-threatening, and Grade 5= Death related to adverse event.

End point type	Primary
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End point timeframe:

Up to Day 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: No inferential statistics was planned for this primary endpoint.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As planned, results for Part B were collected separately for M254 and IVIg for each arm in Part B, and combined results were collected for Part C.

End point values	Part A: Placebo	Part A: M254 3 milligrams/kilogram (mg/kg)	Part A: M254 10 mg/kg	Part A: M254 30 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: subjects	6	3	3	3

End point values	Part A: M254 60 mg/kg	Part A: M254 120 mg/kg	Part A: M254 250 mg/kg	Part B: M254 20 mg/kg - M254 period
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	3	3	3	2
Units: subjects	0	3	3	1

End point values	Part B: M254 20 mg/kg - IVIg period	Part B: M254 60 mg/kg - M254 period	Part B: M254 60 mg/kg - IVIg period	Part B: M254 120 mg/kg - M254 period
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2	5	4	5
Units: subjects	0	2	2	1

End point values	Part B: M254	Part B: M254	Part B: M254	Part C: M254
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	120 mg/kg - IVIg period	250 mg/kg - M254 period	250 mg/kg - IVIg period	120 mg/kg and IVIg 1000 mg/kg - M254 period
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	2	2	6
Units: subjects	1	0	0	1

End point values	Part C: M254 120 mg/kg and IVIg 1000 mg/kg - IVIg period	Part C: IVIg 1000 mg/kg and M254 120 mg/kg - IVIg period	Part C: IVIg 1000 mg/kg and M254 120 mg/kg - M254 period	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	5	5	5	
Units: subjects	0	2	2	

Statistical analyses

No statistical analyses for this end point

Primary: Parts A, B, and C: Number of Subjects with Clinically Significant Abnormalities in Clinical Laboratory Values

End point title	Parts A, B, and C: Number of Subjects with Clinically Significant Abnormalities in Clinical Laboratory Values ^[3]
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End point description:

Number of subjects with clinically significant laboratory abnormalities (chemistry, hematology, and coagulation) were reported. Safety analysis set included all subjects who received at least 1 dose of M254 or IVIg or placebo.

End point type	Primary
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End point timeframe:

Up to Day 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: No inferential statistics was planned for this primary endpoint.

End point values	Part A: Placebo	Part A: M254 3 milligrams/kilo gram (mg/kg)	Part A: M254 10 mg/kg	Part A: M254 30 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: subjects	0	0	0	0

End point values	Part A: M254 60 mg/kg	Part A: M254 120 mg/kg	Part A: M254 250 mg/kg	Part B: M254 20 mg/kg and IV immunoglobuli n (IVIg) 1000
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				mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	2
Units: subjects	0	0	0	0

End point values	Part B: M254 60 mg/kg and IVIg 1000 mg/kg	Part B: M254 120 mg/kg and IVIg 1000 mg/kg	Part B: M254 250 mg/kg and IVIg 1000 mg/kg	Part C: M254 120 mg/kg and IVIg 1000 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	6
Units: subjects	0	0	0	0

End point values	Part C: IVIg 1000 mg/kg and M254 120 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: subjects	0			

Statistical analyses

No statistical analyses for this end point

Primary: Parts A, B, and C: Number of Subjects with Clinically Significant Abnormalities in Vital Signs

End point title	Parts A, B, and C: Number of Subjects with Clinically Significant Abnormalities in Vital Signs ^[4]
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End point description:

Number of subjects with clinically significant abnormalities in vital signs (blood pressure, pulse rate, respiratory rate, and body temperature) were reported. Safety analysis set included all subjects who received at least 1 dose of M254 or IVIg or placebo.

End point type	Primary
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End point timeframe:

Up 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: No inferential statistics was planned for this primary endpoint.

End point values	Part A: Placebo	Part A: M254 3 milligrams/kilogram (mg/kg)	Part A: M254 10 mg/kg	Part A: M254 30 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: subjects	0	0	0	0

End point values	Part A: M254 60 mg/kg	Part A: M254 120 mg/kg	Part A: M254 250 mg/kg	Part B: M254 20 mg/kg and IV immunoglobulin (IVIg) 1000 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	2
Units: subjects	0	0	1	0

End point values	Part B: M254 60 mg/kg and IVIg 1000 mg/kg	Part B: M254 120 mg/kg and IVIg 1000 mg/kg	Part B: M254 250 mg/kg and IVIg 1000 mg/kg	Part C: M254 120 mg/kg and IVIg 1000 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	6
Units: subjects	0	0	0	0

End point values	Part C: IVIg 1000 mg/kg and M254 120 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: subjects	1			

Statistical analyses

No statistical analyses for this end point

Primary: Parts A, B, and C: Number of Subjects with Clinically Significant Abnormalities in Electrocardiograms (ECGs)

End point title	Parts A, B, and C: Number of Subjects with Clinically Significant Abnormalities in Electrocardiograms (ECGs) ^[5]
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End point description:

Number of subjects with clinically significant abnormalities in ECGs were reported. Safety analysis set included all subjects who received at least 1 dose of M254 or IVIg or placebo.

End point type	Primary
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End point timeframe:

Up to Day 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: No inferential statistics was planned for this primary endpoint.

End point values	Part A: Placebo	Part A: M254 3 milligrams/kilogram (mg/kg)	Part A: M254 10 mg/kg	Part A: M254 30 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: subjects	0	0	0	0

End point values	Part A: M254 60 mg/kg	Part A: M254 120 mg/kg	Part A: M254 250 mg/kg	Part B: M254 20 mg/kg and IV immunoglobulin (IVIg) 1000 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	2
Units: subjects	0	0	0	0

End point values	Part B: M254 60 mg/kg and IVIg 1000 mg/kg	Part B: M254 120 mg/kg and IVIg 1000 mg/kg	Part B: M254 250 mg/kg and IVIg 1000 mg/kg	Part C: M254 120 mg/kg and IVIg 1000 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	6
Units: subjects	0	0	0	0

End point values	Part C: IVIg 1000 mg/kg and M254 120 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: subjects	0			

Statistical analyses

No statistical analyses for this end point

Primary: Part C: Number of Subjects with Overall Platelet Response After M254 Administration Compared to IVIg

End point title	Part C: Number of Subjects with Overall Platelet Response After M254 Administration Compared to IVIg ^[6]
End point description: Number of subjects with overall platelet response after M254 administration compared to IVIg were reported. Overall platelet response rate is defined as reaching the therapeutic platelet count. A therapeutic platelet count is defined as greater than or equal to (\geq) $50 \times 10^9/\text{litre (L)}$ and an increase from baseline of $\geq 20 \times 10^9/\text{L}$. The full analysis set consisted of all subjects who were included in the safety set for whom at least 1 post-infusion pharmacodynamics (PD) assessment was completed. Here, N (number of subjects analysed) indicates number of subjects evaluable for this endpoint.	
End point type	Primary
End point timeframe: Up to Day 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: No inferential statistics was planned for this primary endpoint.	

End point values	Part C: M254 120 mg/kg	Part C: IVIg 1000 mg/kg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	11	10		
Units: subjects	8	9		

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A, B, and C: Maximum Observed Plasma Concentration (Cmax) of M254

End point title	Parts A, B, and C: Maximum Observed Plasma Concentration (Cmax) of M254 ^[7]
End point description: Cmax is defined as the maximum observed plasma concentration of M254. PK data analysis set included all subjects who received at least 1 dose of M254 or IVIg or placebo with at least 4 evaluable data points adequate to create an evaluable plasma concentration profile. Here, 99999 signifies that as planned, the data was not collected for arms where total number of subjects for a treatment was lower than 3.	
End point type	Secondary
End point timeframe: Up to Day 29	
Notes: [7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: As planned, results for Part B were collected separately for M254 and IVIg for each arm in Part B, and combined results were collected for Part C.	

End point values	Part A: Placebo	Part A: M254 3 milligrams/kilo gram (mg/kg)	Part A: M254 10 mg/kg	Part A: M254 30 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: micrograms per millilitre (mcg/mL)				
geometric mean (full range (min-max))	2.55 (0.600 to 6.10)	53.5 (51.5 to 55.3)	193 (172 to 242)	588 (532 to 664)

End point values	Part A: M254 60 mg/kg	Part A: M254 120 mg/kg	Part A: M254 250 mg/kg	Part B: M254 20 mg/kg and IV immunoglobulin (IVIg) 1000 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	2
Units: micrograms per millilitre (mcg/mL)				
geometric mean (full range (min-max))	1244 (1148 to 1351)	2722 (2423 to 3099)	5123 (3910 to 6316)	99999 (99999 to 99999)

End point values	Part B: M254 60 mg/kg and IVIg 1000 mg/kg	Part B: M254 120 mg/kg and IVIg 1000 mg/kg	Part B: M254 250 mg/kg and IVIg 1000 mg/kg	Part C: M254 120 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	5	5	2	11
Units: micrograms per millilitre (mcg/mL)				
geometric mean (full range (min-max))	1178 (728 to 1724)	2794 (2480 to 3548)	99999 (99999 to 99999)	3464 (2341 to 6008)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A, B, and C: Time to Reach Maximum Observed Plasma Concentration (Tmax) of M254

End point title	Parts A, B, and C: Time to Reach Maximum Observed Plasma Concentration (Tmax) of M254 ^[8]
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End point description:

Tmax is defined as the time to reach the maximum plasma concentration of M254. PK data analysis set included all subjects who received at least 1 dose of M254 or IVIg or placebo with at least 4 evaluable data points adequate to create an evaluable plasma concentration profile.

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: As planned, results for Part B were collected separately for M254 and IVIg for each arm in Part B, and combined results were collected for Part C.

End point values	Part A: Placebo	Part A: M254 3 milligrams/kilogram (mg/kg)	Part A: M254 10 mg/kg	Part A: M254 30 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: hours				
median (full range (min-max))	338.68 (336.98 to 507.73)	0.60 (0.60 to 1.10)	0.45 (0.43 to 2.33)	0.77 (0.77 to 1.03)

End point values	Part A: M254 60 mg/kg	Part A: M254 120 mg/kg	Part A: M254 250 mg/kg	Part B: M254 20 mg/kg and IV immunoglobulin (IVIg) 1000 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	2
Units: hours				
median (full range (min-max))	1.23 (1.20 to 3.18)	1.83 (1.70 to 2.63)	2.62 (2.40 to 2.67)	1.02 (0.87 to 1.17)

End point values	Part B: M254 60 mg/kg and IVIg 1000 mg/kg	Part B: M254 120 mg/kg and IVIg 1000 mg/kg	Part B: M254 250 mg/kg and IVIg 1000 mg/kg	Part C: M254 120 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	5	5	2	11
Units: hours				
median (full range (min-max))	1.48 (1.12 to 1.67)	1.93 (1.67 to 2.07)	2.74 (2.53 to 2.95)	1.85 (1.60 to 2.13)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A and B, and C: Area Under the Plasma Concentration-time Curve from Time Zero to Infinite Time (AUC[0-infinity]) of M254

End point title	Parts A and B, and C: Area Under the Plasma Concentration-time Curve from Time Zero to Infinite Time (AUC[0-infinity]) of M254 ^[9]
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End point description:

AUC (0-infinity) is defined as area under the plasma concentration-time curve from time 0 to infinite time of M254. PK data analysis set included all subjects who received at least 1 dose of M254 or IVIg or placebo with at least 4 evaluable data points adequate to create an evaluable plasma concentration profile. Here, 99999 signifies that the data could not be calculated due to insufficient data available for reliable parameter calculation (Part A: Placebo); and as planned, the data was not collected for arms where total number of subjects for a treatment was lower than 3 (Part B: M254 20 mg/kg and IV immunoglobulin (IVIg) 1000 mg/kg and Part B: M254 250 mg/kg and IVIg 1000 mg/kg).

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As planned, results for Part B were collected separately for M254 and IVIg for each arm in Part B, and combined results were collected for Part C.

End point values	Part A: Placebo	Part A: M254 3 milligrams/kilogram (mg/kg)	Part A: M254 10 mg/kg	Part A: M254 30 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: h*micrograms per millilitre (h*mcg/mL)				
geometric mean (full range (min-max))	99999 (99999 to 99999)	18944 (12867 to 24589)	75279 (68012 to 87057)	211644 (201291 to 223299)

End point values	Part A: M254 60 mg/kg	Part A: M254 120 mg/kg	Part A: M254 250 mg/kg	Part B: M254 20 mg/kg and IV immunoglobulin (IVIg) 1000 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	2
Units: h*micrograms per millilitre (h*mcg/mL)				
geometric mean (full range (min-max))	604174 (521893 to 654506)	1166585 (997104 to 1351535)	2082296 (1568703 to 2620469)	99999 (99999 to 99999)

End point values	Part B: M254 60 mg/kg and IVIg 1000 mg/kg	Part B: M254 120 mg/kg and IVIg 1000 mg/kg	Part B: M254 250 mg/kg and IVIg 1000 mg/kg	Part C: M254 120 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	5	5	2	11
Units: h*micrograms per millilitre (h*mcg/mL)				
geometric mean (full range (min-max))	404424 (281920 to 527941)	913565 (847526 to 1000004)	99999 (99999 to 99999)	1073227 (693431 to 1377293)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A, B, and C: Area Under the Plasma Concentration-time Curve From Time Zero to Time of Last Quantifiable Concentration (AUC[0-last]) of M254

End point title	Parts A, B, and C: Area Under the Plasma Concentration-time Curve From Time Zero to Time of Last Quantifiable Concentration (AUC[0-last]) of M254 ^[10]
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End point description:

AUC (0-last) is defined as area under the plasma concentration-time curve from time 0 to time of the last quantifiable concentration of M254. AUC (0-last) is calculated by linear-linear trapezoidal summation. PK data analysis set included all subjects who received at least 1 dose of M254 or IVIg or placebo with at least 4 evaluable data points adequate to create an evaluable plasma concentration profile. Here, 99999 signifies that as planned, the data was not collected for arms where total number of subjects for a treatment was lower than 3.

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As planned, results for Part B were collected separately for M254 and IVIg for each arm in Part B, and combined results were collected for Part C.

End point values	Part A: Placebo	Part A: M254 3 milligrams/kilogram (mg/kg)	Part A: M254 10 mg/kg	Part A: M254 30 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: mcg*h/mL				
geometric mean (full range (min-max))	489 (52.5 to 1441)	11268 (9770 to 12701)	40883 (36176 to 47809)	112875 (105884 to 121740)

End point values	Part A: M254 60 mg/kg	Part A: M254 120 mg/kg	Part A: M254 250 mg/kg	Part B: M254 20 mg/kg and IV immunoglobulin (IVIg) 1000 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	2
Units: mcg*h/mL				
geometric mean (full range (min-max))	282488 (251122 to 329379)	661753 (630464 to 704177)	1192832 (996669 to 1315203)	99999 (99999 to 99999)

End point values	Part B: M254 60 mg/kg and IVIg 1000 mg/kg	Part B: M254 120 mg/kg and IVIg 1000 mg/kg	Part B: M254 250 mg/kg and IVIg 1000 mg/kg	Part C: M254 120 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	5	5	2	11
Units: mcg*h/mL				
geometric mean (full range (min-max))	279072 (159477 to 415464)	590785 (546849 to 656664)	99999 (99999 to 99999)	708864 (475511 to 1041499)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A, B, and C: Apparent Terminal Phase Half-life (t_{1/2}) of M254

End point title	Parts A, B, and C: Apparent Terminal Phase Half-life (t _{1/2}) of M254 ^[11]
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End point description:

t_{1/2} is defined as the time measured for the plasma concentration to decrease by 1 half to its original concentration of M254. PK data analysis set included all subjects who received at least 1 dose of M254 or IVIg or placebo with at least 4 evaluable data points adequate to create an evaluable plasma concentration profile. Here, 99999 signifies that the data could not be calculated due to insufficient data available for reliable parameter calculation (Part A: Placebo); and as planned, the data was not collected for arms where total number of subjects for a treatment was lower than 3 (Part B: M254 20 mg/kg and IV immunoglobulin (IVIg) 1000 mg/kg and Part B: M254 250 mg/kg and IVIg 1000 mg/kg).

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As planned, results for Part B were collected separately for M254 and IVIg for each arm in Part B, and combined results were collected for Part C.

End point values	Part A: Placebo	Part A: M254 3 milligrams/kilogram (mg/kg)	Part A: M254 10 mg/kg	Part A: M254 30 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	3	3
Units: hours				
geometric mean (full range (min-max))	99999 (99999 to 99999)	379 (239 to 488)	463 (412 to 520)	481 (405 to 530)

End point values	Part A: M254 60 mg/kg	Part A: M254 120 mg/kg	Part A: M254 250 mg/kg	Part B: M254 20 mg/kg and IV immunoglobulin (IVIg) 1000 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	2
Units: hours				
geometric mean (full range (min-max))	616 (565 to 679)	588 (468 to 660)	590 (493 to 762)	99999 (99999 to 99999)

End point values	Part B: M254 60 mg/kg and IVIg 1000 mg/kg	Part B: M254 120 mg/kg and IVIg 1000 mg/kg	Part B: M254 250 mg/kg and IVIg 1000 mg/kg	Part C: M254 120 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	5	5	2	11
Units: hours				
geometric mean (full range (min-max))	475 (427 to 525)	480 (399 to 595)	99999 (99999 to 99999)	410 (254 to 696)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A, B, and C: Volume of Distribution (Vz) of M254

End point title	Parts A, B, and C: Volume of Distribution (Vz) of M254 ^[12]
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End point description:

Vz is defined as volume of distribution of M254 at terminal phase. PK data analysis set included all subjects who received at least 1 dose of M254 or IVIg or placebo with at least 4 evaluable data points adequate to create an evaluable plasma concentration profile. Here, N (number of subjects analysed) indicates number of subjects evaluable for this endpoint. Here, "99999" signifies that the data could not be calculated due to low sample size.

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As planned, results for Part B were collected separately for M254 and IVIg for each arm in Part B, and combined results were collected for Part C.

End point values	Part A: M254 3 milligrams/kilogram (mg/kg)	Part A: M254 10 mg/kg	Part A: M254 30 mg/kg	Part A: M254 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: mL				
arithmetic mean (standard deviation)	6825 (± 781)	6490 (± 790)	5986 (± 1870)	6975 (± 267)

End point values	Part A: M254 120 mg/kg	Part A: M254 250 mg/kg	Part B: M254 20 mg/kg and IV immunoglobulin (IVIg) 1000 mg/kg	Part B: M254 60 mg/kg and IVIg 1000 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	2	4
Units: mL				
arithmetic mean (standard deviation)	5937 (± 847)	7475 (± 2124)	8679 (± 99999)	9367 (± 4634)

End point values	Part B: M254 120 mg/kg and IVIg 1000 mg/kg	Part B: M254 250 mg/kg and IVIg 1000 mg/kg	Part C: M254 120 mg/kg	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	1	10	
Units: mL				
arithmetic mean (standard deviation)	6916 (± 1223)	99999 (± 99999)	5997 (± 1887)	

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A, B, and C: Clearance (CL) of M254

End point title	Parts A, B, and C: Clearance (CL) of M254 ^[13]
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End point description:

CL is defined as clearance of M254, calculated as dose/AUC (0-infinity). PK data analysis set included all subjects who received at least 1 dose of M254 or IVIg or placebo with at least 4 evaluable data points adequate to create an evaluable plasma concentration profile. Here, N (number of subjects analyzed) indicates number of subjects evaluable for this endpoint. Here, "99999" signifies that the data could not be calculated due to low sample size.

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As planned, results for Part B were collected separately for M254 and IVIg for each arm in Part B, and combined results were collected for Part C.

End point values	Part A: M254 3 milligrams/kilogram (mg/kg)	Part A: M254 10 mg/kg	Part A: M254 30 mg/kg	Part A: M254 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: millilitre/hour				
arithmetic mean (standard deviation)	13.7 (± 7.60)	9.69 (± 0.730)	8.49 (± 1.79)	7.87 (± 0.745)

End point values	Part A: M254 120 mg/kg	Part A: M254 250 mg/kg	Part B: M254 20 mg/kg and IV immunoglobulin (IVIg) 1000 mg/kg	Part B: M254 60 mg/kg and IVIg 1000 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	2	4

Units: millilitre/hour				
arithmetic mean (standard deviation)	7.16 (± 2.14)	9.16 (± 4.26)	15.6 (± 99999)	13.2 (± 5.33)

End point values	Part B: M254 120 mg/kg and IVIg 1000 mg/kg	Part B: M254 250 mg/kg and IVIg 1000 mg/kg	Part C: M254 120 mg/kg	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	1	10	
Units: millilitre/hour				
arithmetic mean (standard deviation)	9.97 (± 1.70)	99999 (± 99999)	9.73 (± 1.72)	

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A, B, and C: Mean Residence Time (MRT) of M254

End point title	Parts A, B, and C: Mean Residence Time (MRT) of M254 ^[14]
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End point description:

Mean residence time is calculated as area under the first moment curve of M254. PK data analysis set included all subjects who received at least 1 dose of M254 or IVIg or placebo with at least 4 evaluable data points adequate to create an evaluable plasma concentration profile. Here, N (number of subjects analyzed) indicates number of subjects evaluable for this endpoint. Here, "99999" signifies that the data could not be calculated due to low sample size.

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As planned, results for Part B were collected separately for M254 and IVIg for each arm in Part B, and combined results were collected for Part C.

End point values	Part A: M254 3 milligrams/kilogram (mg/kg)	Part A: M254 10 mg/kg	Part A: M254 30 mg/kg	Part A: M254 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: hours				
arithmetic mean (standard deviation)	570 (± 190)	654 (± 75.9)	676 (± 107)	867 (± 79.8)

End point values	Part A: M254 120 mg/kg	Part A: M254 250 mg/kg	Part B: M254 20 mg/kg and IV immunoglobulin (IVIg) 1000 mg/kg	Part B: M254 60 mg/kg and IVIg 1000 mg/kg
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	2	4
Units: hours				
arithmetic mean (standard deviation)	820 (± 163)	818 (± 189)	517 (± 99999)	661 (± 77.0)

End point values	Part B: M254 120 mg/kg and IVIg 1000 mg/kg	Part B: M254 250 mg/kg and IVIg 1000 mg/kg	Part C: M254 120 mg/kg	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	1	10	
Units: hours				
arithmetic mean (standard deviation)	653 (± 109)	99999 (± 99999)	584 (± 177)	

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A and B, and C: Percentage of the Estimated Part for the Calculation of AUC0-inf (%AUCextra) of M254

End point title	Parts A and B, and C: Percentage of the Estimated Part for the Calculation of AUC0-inf (%AUCextra) of M254 ^[15]
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End point description:

Percentage of the estimated part for the calculation of AUC0-inf (%AUCextra) of M254 were reported. PK data analysis set included all subjects who received at least 1 dose of M254 or IVIg or placebo with at least 4 evaluable data points adequate to create an evaluable plasma concentration profile. Here, N (number of subjects analyzed) indicates number of subjects evaluable for this endpoint. Here, "99999" signifies that the data could not be calculated due to low sample size.

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As planned, results for Part B were collected separately for M254 and IVIg for each arm in Part B, and combined results were collected for Part C.

End point values	Part A: M254 3 milligrams/kilo gram (mg/kg)	Part A: M254 10 mg/kg	Part A: M254 30 mg/kg	Part A: M254 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: percent				
arithmetic mean (standard deviation)	39.6 (± 13.4)	45.6 (± 4.0)	46.4 (± 6.0)	53.1 (± 4.2)

End point values	Part A: M254 120 mg/kg	Part A: M254 250 mg/kg	Part B: M254 20 mg/kg and	Part B: M254 60 mg/kg and
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			IV immunoglobulin (IVIg) 1000 mg/kg	IVIg 1000 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	2	4
Units: percent				
arithmetic mean (standard deviation)	43.0 (± 7.4)	42.4 (± 7.3)	27.2 (± 99999)	37.3 (± 5.8)

End point values	Part B: M254 120 mg/kg and IVIg 1000 mg/kg	Part B: M254 250 mg/kg and IVIg 1000 mg/kg	Part C: M254 120 mg/kg	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	1	10	
Units: percent				
arithmetic mean (standard deviation)	35.1 (± 5.5)	99999 (± 99999)	30.5 (± 10.2)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Day 29

Adverse event reporting additional description:

The safety analysis set included all subjects who received at least 1 dose of M254 or IVIg or placebo.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.0
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Reporting groups

Reporting group title	Part A: Placebo
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Reporting group description:

Subjects received a single intravenous (IV) infusion of matching placebo on Day 1.

Reporting group title	Part A: M254 3 milligrams/kilogram (mg/kg)
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Reporting group description:

Subjects received a single IV infusion of M254 3 mg/kg on Day 1.

Reporting group title	Part A: M254 10 mg/kg
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Reporting group description:

Subjects received a single IV infusion of M254 10 mg/kg on Day 1.

Reporting group title	Part A: M254 30 mg/kg
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Reporting group description:

Subjects received a single IV infusion of M254 30 mg/kg on Day 1.

Reporting group title	Part A: M254 60 mg/kg
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Reporting group description:

Subjects received a single IV infusion of M254 60 mg/kg on Day 1.

Reporting group title	Part A: M254 120 mg/kg
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Reporting group description:

Subjects received a single IV infusion of M254 120 mg/kg on Day 1.

Reporting group title	Part A: M254 250 mg/kg
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Reporting group description:

Subjects received a single IV infusion of M254 250 mg/kg on Day 1.

Reporting group title	Part B: M254 20 mg/kg - M254 period
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Reporting group description:

Subjects with immune thrombocytopenia purpura (ITP) received a single intravenous (IV) infusion of M254 20 milligrams/kilogram (mg/kg) on Day 1.

Reporting group title	Part B: M254 20 mg/kg - IVIg period
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Reporting group description:

Subjects with ITP received a single IV infusion of IV immunoglobulin (IVIg) 1000 mg/kg on Day 29.

Reporting group title	Part B: M254 60 mg/kg - M254 period
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Reporting group description:

Subjects with ITP received a single IV infusion of M254 60 mg/kg on Day 1.

Reporting group title	Part B: M254 60 mg/kg - IVIg period
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Reporting group description:

Subjects with ITP received a single IV infusion of IVIg 1000 mg/kg on Day 29.

Reporting group title	Part B: M254 120 mg/kg - M254 period
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Reporting group description:

Subjects with ITP received a single IV infusion of M254 120 mg/kg on Day 1.

Reporting group title	Part B: M254 120 mg/kg - IVIg period
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Reporting group description:

Subjects with ITP received a single IV infusion of IVIg 1000 mg/kg on Day 29.

Reporting group title	Part B: M254 250 mg/kg - M254 period
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Reporting group description:

Subjects with ITP received a single IV infusion of M254 250 mg/kg on Day 1.

Reporting group title	Part B: M254 250 mg/kg - IVIg period
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Reporting group description:

Subjects with ITP received a single IV infusion of IVIg 1000 mg/kg on Day 29.

Reporting group title	Part C: M254 120 mg/kg and IVIg 1000 mg/kg - M254 period
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Reporting group description:

Subjects with ITP received a single IV infusion of M254 120 mg/kg on Day 1.

Reporting group title	Part C: M254 120 mg/kg and IVIg 1000 mg/kg - IVIg period
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Reporting group description:

Subjects with ITP received a single IV infusion of IVIg 1000 mg/kg on Day 29.

Reporting group title	Part C: IVIg 1000 mg/kg and M254 120 mg/kg - IVIg period
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Reporting group description:

Subjects with ITP received a single IV infusion of IVIg 1000 mg/kg on Day 1.

Reporting group title	Part C: IVIg 1000 mg/kg and M254 120 mg/kg - M254 period
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Reporting group description:

Subjects with ITP received a single IV infusion of M254 120 mg/kg on Day 1.

Serious adverse events	Part A: Placebo	Part A: M254 3 milligrams/kilogram (mg/kg)	Part A: M254 10 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	Part A: M254 30 mg/kg	Part A: M254 60 mg/kg	Part A: M254 120 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	Part A: M254 250 mg/kg	Part B: M254 20 mg/kg - M254 period	Part B: M254 20 mg/kg - IVIg period
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	Part B: M254 60 mg/kg - M254 period	Part B: M254 60 mg/kg - IVIg period	Part B: M254 120 mg/kg - M254 period
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	Part B: M254 120 mg/kg - IVIg period	Part B: M254 250 mg/kg - M254 period	Part B: M254 250 mg/kg - IVIg period
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	Part C: M254 120 mg/kg and IVIg 1000 mg/kg - M254 period	Part C: M254 120 mg/kg and IVIg 1000 mg/kg - IVIg period	Part C: IVIg 1000 mg/kg and M254 120 mg/kg - IVIg period
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	Part C: IVIg 1000 mg/kg and M254 120 mg/kg - M254 period		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	Part A: Placebo	Part A: M254 3 milligrams/kilogram (mg/kg)	Part A: M254 10 mg/kg
Total subjects affected by non-serious adverse events subjects affected / exposed	6 / 7 (85.71%)	3 / 3 (100.00%)	3 / 3 (100.00%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Catheter Site Bruise			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Catheter Site Haematoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter Site Related Reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Feeling Hot			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion Site Haematoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion Site Reaction			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion Site Swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Medical Device Site Irritation			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oedema Peripheral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vessel Puncture Site Bruise			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vessel Puncture Site Haematoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vessel Puncture Site Reaction			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal Congestion			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Nasal Dryness subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Investigations Platelet Count Decreased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Injury, poisoning and procedural complications Contusion subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Infusion Related Reaction subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Limb Injury subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Road Traffic Accident subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 4	3 / 3 (100.00%) 3	0 / 3 (0.00%) 0
Blood and lymphatic system disorders Neutropenia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0

Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Gastrointestinal disorders			
Abdominal Pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Constipation subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Dyspepsia subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Faeces Soft subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Nausea subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 3	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Skin and subcutaneous tissue disorders			
Dermatitis Contact subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Dry Skin subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Skin Irritation subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Renal and urinary disorders			

Pollakiuria subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Back Pain subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Bone Pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Pain in Extremity subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Infections and infestations			
Bronchitis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Cystitis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Nasopharyngitis subjects affected / exposed occurrences (all)	4 / 7 (57.14%) 5	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Metabolism and nutrition disorders			
Decreased Appetite subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Iron Deficiency subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0

Vitamin B12 Deficiency subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
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Non-serious adverse events	Part A: M254 30 mg/kg	Part A: M254 60 mg/kg	Part A: M254 120 mg/kg
Total subjects affected by non-serious adverse events subjects affected / exposed	3 / 3 (100.00%)	0 / 3 (0.00%)	3 / 3 (100.00%)
Vascular disorders			
Flushing subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
General disorders and administration site conditions			
Catheter Site Bruise subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Catheter Site Haematoma subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Catheter Site Related Reaction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Chills subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Feeling Hot subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Influenza Like Illness subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1

Infusion Site Haematoma subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Infusion Site Reaction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Infusion Site Swelling subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Medical Device Site Irritation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Oedema Peripheral subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Vessel Puncture Site Bruise subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Vessel Puncture Site Haematoma subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Vessel Puncture Site Reaction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Epistaxis			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Nasal Congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal Dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Investigations			
Platelet Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion Related Reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Limb Injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Road Traffic Accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 3 (66.67%)
occurrences (all)	1	0	3
Blood and lymphatic system disorders			

Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Faeces Soft			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis Contact			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry Skin			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Skin Irritation			

subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Renal and urinary disorders Pollakiuria subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Musculoskeletal and connective tissue disorders Back Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Bone Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Pain in Extremity subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Cystitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Metabolism and nutrition disorders Decreased Appetite subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1

Iron Deficiency subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Vitamin B12 Deficiency subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0

Non-serious adverse events	Part A: M254 250 mg/kg	Part B: M254 20 mg/kg - M254 period	Part B: M254 20 mg/kg - IVIg period
Total subjects affected by non-serious adverse events subjects affected / exposed	3 / 3 (100.00%)	1 / 2 (50.00%)	0 / 2 (0.00%)
Vascular disorders			
Flushing subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
General disorders and administration site conditions			
Catheter Site Bruise subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Catheter Site Haematoma subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Catheter Site Related Reaction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Chills subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Feeling Hot subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0

Influenza Like Illness subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Infusion Site Haematoma subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Infusion Site Reaction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Infusion Site Swelling subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Medical Device Site Irritation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Oedema Peripheral subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Vessel Puncture Site Bruise subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Vessel Puncture Site Haematoma subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Vessel Puncture Site Reaction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			

Cough subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Nasal Congestion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Nasal Dryness subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Investigations Platelet Count Decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 2 (50.00%) 1	0 / 2 (0.00%) 0
Injury, poisoning and procedural complications Contusion subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Infusion Related Reaction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Limb Injury subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Road Traffic Accident subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0

Headache subjects affected / exposed occurrences (all)	3 / 3 (100.00%) 3	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Blood and lymphatic system disorders			
Neutropenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Gastrointestinal disorders			
Abdominal Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Faeces Soft subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Skin and subcutaneous tissue disorders			
Dermatitis Contact subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Dry Skin			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Skin Irritation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Renal and urinary disorders Pollakiuria subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Musculoskeletal and connective tissue disorders Back Pain subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Bone Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Pain in Extremity subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Cystitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Metabolism and nutrition disorders			

Decreased Appetite subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Iron Deficiency subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Vitamin B12 Deficiency subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0

Non-serious adverse events	Part B: M254 60 mg/kg - M254 period	Part B: M254 60 mg/kg - IVIg period	Part B: M254 120 mg/kg - M254 period
Total subjects affected by non-serious adverse events subjects affected / exposed	2 / 5 (40.00%)	2 / 4 (50.00%)	1 / 5 (20.00%)
Vascular disorders			
Flushing subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
General disorders and administration site conditions			
Catheter Site Bruise subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Catheter Site Haematoma subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Catheter Site Related Reaction subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Chills subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0

Feeling Hot			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Influenza Like Illness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infusion Site Haematoma			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Infusion Site Reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infusion Site Swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Medical Device Site Irritation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vessel Puncture Site Bruise			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vessel Puncture Site Haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Vessel Puncture Site Reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 4 (25.00%) 1	0 / 5 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Nasal Congestion subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Nasal Dryness subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 4 (25.00%) 1	0 / 5 (0.00%) 0
Investigations			
Platelet Count Decreased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 3	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Infusion Related Reaction subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Limb Injury subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Road Traffic Accident subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0

Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 5 (0.00%)	2 / 4 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Faeces Soft			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	2 / 4 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	3	0
Skin and subcutaneous tissue disorders			

Dermatitis Contact subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Dry Skin subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Skin Irritation subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Renal and urinary disorders Pollakiuria subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Musculoskeletal and connective tissue disorders Back Pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Bone Pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	1 / 5 (20.00%) 1
Myalgia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Pain in Extremity subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Cystitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0

Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Metabolism and nutrition disorders			
Decreased Appetite subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Iron Deficiency subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0
Vitamin B12 Deficiency subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0

Non-serious adverse events	Part B: M254 120 mg/kg - IVIg period	Part B: M254 250 mg/kg - M254 period	Part B: M254 250 mg/kg - IVIg period
Total subjects affected by non-serious adverse events subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 2 (0.00%)
Vascular disorders			
Flushing subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
General disorders and administration site conditions			
Catheter Site Bruise subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Catheter Site Haematoma subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Catheter Site Related Reaction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Chills			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Feeling Hot			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion Site Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion Site Reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion Site Swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Medical Device Site Irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vessel Puncture Site Bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vessel Puncture Site Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vessel Puncture Site Reaction			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Epistaxis subjects affected / exposed occurrences (all) Nasal Congestion subjects affected / exposed occurrences (all) Nasal Dryness subjects affected / exposed occurrences (all) Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0	0 / 2 (0.00%) 0 0 / 2 (0.00%) 0 0 / 2 (0.00%) 0 0 / 2 (0.00%) 0	0 / 2 (0.00%) 0 0 / 2 (0.00%) 0 0 / 2 (0.00%) 0 0 / 2 (0.00%) 0
Investigations Platelet Count Decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Injury, poisoning and procedural complications Contusion subjects affected / exposed occurrences (all) Infusion Related Reaction subjects affected / exposed occurrences (all) Limb Injury	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0	0 / 2 (0.00%) 0 0 / 2 (0.00%) 0	0 / 2 (0.00%) 0 0 / 2 (0.00%) 0

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Road Traffic Accident subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Blood and lymphatic system disorders Neutropenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Gastrointestinal disorders Abdominal Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Faeces Soft subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Nausea			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Skin and subcutaneous tissue disorders Dermatitis Contact subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Dry Skin subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Skin Irritation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Renal and urinary disorders Pollakiuria subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Musculoskeletal and connective tissue disorders Back Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Bone Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Pain in Extremity subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0
Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0

Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Iron Deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 Deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part C: M254 120 mg/kg and IVIg 1000 mg/kg - M254 period	Part C: M254 120 mg/kg and IVIg 1000 mg/kg - IVIg period	Part C: IVIg 1000 mg/kg and M254 120 mg/kg - IVIg period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	2 / 5 (40.00%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Catheter Site Bruise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Catheter Site Haematoma			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Catheter Site Related Reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Feeling Hot			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infusion Site Haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infusion Site Reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infusion Site Swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Medical Device Site Irritation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vessel Puncture Site Bruise			

subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Vessel Puncture Site Haematoma subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Vessel Puncture Site Reaction subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Nasal Congestion subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Nasal Dryness subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Investigations Platelet Count Decreased subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Injury, poisoning and procedural complications Contusion			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infusion Related Reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Limb Injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Road Traffic Accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			

subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Faeces Soft			
subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Nausea			
subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Vomiting			
subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Skin and subcutaneous tissue disorders			
Dermatitis Contact			
subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Dry Skin			
subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Skin Irritation			
subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Bone Pain			
subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Myalgia			
subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Pain in Extremity			

subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 5 (0.00%) 0	1 / 5 (20.00%) 1
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iron Deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 Deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part C: IVIg 1000 mg/kg and M254 120 mg/kg - M254 period		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 5 (40.00%)		
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		

General disorders and administration site conditions			
Catheter Site Bruise			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Catheter Site Haematoma			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Catheter Site Related Reaction			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Chills			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Fatigue			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Feeling Hot			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Influenza Like Illness			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Infusion Site Haematoma			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Infusion Site Reaction			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Infusion Site Swelling			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Medical Device Site Irritation			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Oedema Peripheral			

<p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p>		
<p>Pyrexia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p>		
<p>Vessel Puncture Site Bruise</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p>		
<p>Vessel Puncture Site Haematoma</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p>		
<p>Vessel Puncture Site Reaction</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p>		
<p>Reproductive system and breast disorders</p> <p>Dysmenorrhoea</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p>		
<p>Respiratory, thoracic and mediastinal disorders</p> <p>Cough</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Epistaxis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Nasal Congestion</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Nasal Dryness</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Rhinorrhoea</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p>		
Investigations			

Platelet Count Decreased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Injury, poisoning and procedural complications Contusion subjects affected / exposed occurrences (all) Infusion Related Reaction subjects affected / exposed occurrences (all) Limb Injury subjects affected / exposed occurrences (all) Road Traffic Accident subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0 0 / 5 (0.00%) 0 0 / 5 (0.00%) 0 0 / 5 (0.00%) 0		
Nervous system disorders Dizziness subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0 0 / 5 (0.00%) 0		
Blood and lymphatic system disorders Neutropenia subjects affected / exposed occurrences (all) Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0 1 / 5 (20.00%) 4		
Gastrointestinal disorders Abdominal Pain subjects affected / exposed occurrences (all) Constipation	0 / 5 (0.00%) 0		

subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Faeces Soft			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Dermatitis Contact			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Dry Skin			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Skin Irritation			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Bone Pain			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Myalgia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Pain in Extremity</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p>		
<p>Infections and infestations</p> <p>Bronchitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Cystitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Nasopharyngitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Upper Respiratory Tract Infection</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p>		
<p>Metabolism and nutrition disorders</p> <p>Decreased Appetite</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Iron Deficiency</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Vitamin B12 Deficiency</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p>		

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Part C (Group 2) and Part D was planned but not conducted based on sponsor decision to discontinue the study after completion of Part A, Part B, and Part C (Group 1). No safety concerns were identified and study was terminated for business reasons.
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Notes: