



## Clinical trial results: Continuos versus periodic intravenous iron supplementation in maintenance hemodialysis patients

### Summary

EudraCT number	2012-003914-15
Trial protocol	AT
Global end of trial date	14 May 2019

### Results information

Result version number	v1 (current)
This version publication date	21 November 2021
First version publication date	21 November 2021

### Trial information

#### Trial identification

Sponsor protocol code	Studienprotokoll/V5.1/01.12.2013
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02198495
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Währinger Gürtel 18-20, Vienn, Austria, 1090
Public contact	Nephrologie und Dialyse, Medizinische Universität Wien, Klinik für Innere Medizin III, Kli Abteilung für Nephrologie und Dia, +43 14040043910, gere.sunder-plassmann@meduniwien.ac.at
Scientific contact	Nephrologie und Dialyse, Medizinische Universität Wien, Klinik für Innere Medizin III, Klin Abteilung für Nephrologie und , +43 14040043910, gere.sunder-plassmann@meduniwien.ac.at

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	06 September 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 May 2019
Global end of trial reached?	Yes
Global end of trial date	14 May 2019
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

Ferric carboxymaltose (Ferinject) in comparison to iron sucrose (Venofer) is non inferior in maintaining the target hemoglobin-level (Hb 10-12 g/dl)

Protection of trial subjects:

Patients were observed at least 30 minutes after injection in order to allow prompt treatment of rare intolerance reactions. Only one occurrence, the patient was discharged well on the same day. As the participating patients were dialysis patients, they were under continuous surveillance during the dialysis session.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 June 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 142
Worldwide total number of subjects	142
EEA total number of subjects	142

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	94
From 65 to 84 years	45
85 years and over	3

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

All patients were screened according to the exclusion/inclusion criteria. The eligible patients were contacted and asked if they agree to participate to the study

### Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Iron sucrose administration

Arm description:

The patients received iron sucrose i.v. 100mg every 2 weeks from baseline to week 40

Arm type	Experimental
Investigational medicinal product name	Iron sucrose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

100 mg every 2 weeks

<b>Arm title</b>	Ferric Carboxymaltose
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Arm description:

Patients received 500 mg Ferric Carboxymaltose i.v. every 10 weeks from baseline to 40 weeks

Arm type	Experimental
Investigational medicinal product name	Ferric Carboxymaltose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

500 mg every 10 weeks

<b>Number of subjects in period 1</b>	Iron sucrose administration	Ferric Carboxymaltose
Started	71	71
Completed	53	55
Not completed	18	16
Adverse event, serious fatal	6	2
Consent withdrawn by subject	4	1

Adverse event, non-fatal	-	1
Lost to follow-up	-	2
Protocol deviation	8	10

## Baseline characteristics

### Reporting groups

Reporting group title	Overall trial
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Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	142	142	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	94	94	
From 65-84 years	45	45	
85 years and over	3	3	
Gender categorical			
Units: Subjects			
Female	41	41	
Male	101	101	

## End points

### End points reporting groups

Reporting group title	Iron sucrose administration
Reporting group description:	The patients received iron sucrose i.v. 100mg every 2 weeks from baseline to week 40
Reporting group title	Ferric Carboxymaltose
Reporting group description:	Patients received 500 mg Ferric Carboxymaltose i.v. every 10 weeks from baseline to 40 weeks

### Primary: The primary endpoint was defined as the difference between hemoglobin level at baseline and week 40

End point title	The primary endpoint was defined as the difference between hemoglobin level at baseline and week 40
End point description:	
End point type	Primary
End point timeframe:	Baseline to 40 weeks

End point values	Iron sucrose administration	Ferric Carboxymaltose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	71		
Units: g/dL				
least squares mean (confidence interval 95%)	-0.27 (-0.64 to 0.09)	-0.74 (-1.10 to -0.39)		

<b>Attachments (see zip file)</b>	SAE Ferinject/Kopie von SAE_Ferinject.xlsx SAE Venofer/Kopie von SAE_Venofer.xlsx
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### Statistical analyses

<b>Statistical analysis title</b>	ANCOVA
Comparison groups	Ferric Carboxymaltose v Iron sucrose administration
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.05
Method	ANCOVA
Parameter estimate	Mean difference (final values)

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**Secondary: Cumulative ESA doses**

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End point title	Cumulative ESA doses
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End point description:

End point type	Secondary
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End point timeframe:

Baseline to week 40

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End point values	Iron sucrose administration	Ferric Carboxymaltose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	68	67		
Units: IU/week				
median (inter-quartile range (Q1-Q3))	6000 (3500 to 12000)	7000 (2300 to 12800)		

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**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Ferritin serum level**

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End point title	Ferritin serum level
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End point description:

End point type	Secondary
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End point timeframe:

Baseline to week 40

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End point values	Iron sucrose administration	Ferric Carboxymaltose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	70		
Units: ng/mL				
least squares mean (confidence interval 98.3%)	-10.1 (-32.1 to 19)	-37.8 (-52.5 to -18.5)		

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**Statistical analyses**

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No statistical analyses for this end point

### Secondary: Hemoglobin level

End point title Hemoglobin level

End point description:

End point type Secondary

End point timeframe:

Baseline to 40 weeks

End point values	Iron sucrose administration	Ferric Carboxymaltose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	70		
Units: g/dl				
least squares mean (confidence interval 95%)	-0.27 (-0.64 to 0.09)	-0.74 (-1.10 to -0.39)		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Transferin Saturation

End point title Transferin Saturation

End point description:

End point type Secondary

End point timeframe:

Baseline to week 40

End point values	Iron sucrose administration	Ferric Carboxymaltose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	70		
Units: procent				
least squares mean (confidence interval 98.3%)	7.1 (-6.8 to 22.9)	-22.2 (-31.9 to -11.1)		

### Statistical analyses

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No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From enrollment to end of study (40 weeks)

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	23
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### Reporting groups

Reporting group title	Venofer
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Reporting group description: -

Reporting group title	Ferinject
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Reporting group description: -

<b>Serious adverse events</b>	Venofer	Ferinject	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 71 (0.00%)	0 / 71 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

<b>Non-serious adverse events</b>	Venofer	Ferinject	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	69 / 71 (97.18%)	13 / 71 (18.31%)	
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 71 (0.00%)	2 / 71 (2.82%)	
occurrences (all)	0	2	
Hypotension			
subjects affected / exposed	2 / 71 (2.82%)	0 / 71 (0.00%)	
occurrences (all)	2	0	
Surgical and medical procedures			
Antibiotic therapy			
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)	
occurrences (all)	1	0	
Coronary angioplasty			

subjects affected / exposed	0 / 71 (0.00%)	1 / 71 (1.41%)	
occurrences (all)	0	1	
Coronary arterial stent insertion			
subjects affected / exposed	0 / 71 (0.00%)	1 / 71 (1.41%)	
occurrences (all)	0	1	
Stent placement			
subjects affected / exposed	1 / 71 (1.41%)	1 / 71 (1.41%)	
occurrences (all)	1	1	
Surgery			
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)	
occurrences (all)	1	0	
Toe amputation			
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)	
occurrences (all)	1	0	
Tooth extraction			
subjects affected / exposed	0 / 71 (0.00%)	1 / 71 (1.41%)	
occurrences (all)	0	1	
Tumour excision			
subjects affected / exposed	0 / 71 (0.00%)	1 / 71 (1.41%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Catheter site inflammation			
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)	
occurrences (all)	1	0	
Chest discomfort			
subjects affected / exposed	0 / 71 (0.00%)	1 / 71 (1.41%)	
occurrences (all)	0	1	
Chest pain			
subjects affected / exposed	2 / 71 (2.82%)	0 / 71 (0.00%)	
occurrences (all)	2	0	
Chills			
subjects affected / exposed	1 / 71 (1.41%)	2 / 71 (2.82%)	
occurrences (all)	1	2	
Fatigue			

subjects affected / exposed	3 / 71 (4.23%)	0 / 71 (0.00%)	
occurrences (all)	5	0	
Inflammation			
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)	
occurrences (all)	1	0	
Necrosis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)	
occurrences (all)	1	0	
Pain			
subjects affected / exposed	3 / 71 (4.23%)	2 / 71 (2.82%)	
occurrences (all)	3	2	
Peripheral swelling			
subjects affected / exposed	0 / 71 (0.00%)	3 / 71 (4.23%)	
occurrences (all)	0	3	
Pyrexia			
subjects affected / exposed	11 / 71 (15.49%)	9 / 71 (12.68%)	
occurrences (all)	11	13	
Swelling face			
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	14 / 71 (19.72%)	11 / 71 (15.49%)	
occurrences (all)	17	15	
Dyspnoea			
subjects affected / exposed	4 / 71 (5.63%)	11 / 71 (15.49%)	
occurrences (all)	4	14	
Nasal polyps			
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)	
occurrences (all)	1	0	
Oropharyngeal pain			
subjects affected / exposed	3 / 71 (4.23%)	4 / 71 (5.63%)	
occurrences (all)	3	4	
Pulmonary hypertension			

subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	1 / 71 (1.41%) 1	
<b>Investigations</b>			
<b>Angiogram</b>			
subjects affected / exposed	1 / 71 (1.41%)	1 / 71 (1.41%)	
occurrences (all)	1	1	
<b>Blood pressure decreased</b>			
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)	
occurrences (all)	1	0	
<b>Catheterisation cardiac</b>			
subjects affected / exposed	0 / 71 (0.00%)	2 / 71 (2.82%)	
occurrences (all)	0	2	
<b>C-reactive protein increased</b>			
subjects affected / exposed	5 / 71 (7.04%)	0 / 71 (0.00%)	
occurrences (all)	5	0	
<b>Haemoglobin decreased</b>			
subjects affected / exposed	2 / 71 (2.82%)	0 / 71 (0.00%)	
occurrences (all)	2	0	
<b>Injury, poisoning and procedural complications</b>			
<b>Arteriovenous fistula site complication</b>			
subjects affected / exposed	0 / 71 (0.00%)	2 / 71 (2.82%)	
occurrences (all)	0	5	
<b>Fall</b>			
subjects affected / exposed	1 / 71 (1.41%)	1 / 71 (1.41%)	
occurrences (all)	1	1	
<b>Joint injury</b>			
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)	
occurrences (all)	1	0	
<b>Postoperative wound complication</b>			
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)	
occurrences (all)	1	0	
<b>Procedural pain</b>			
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)	
occurrences (all)	1	0	
<b>Shunt thrombosis</b>			

subjects affected / exposed occurrences (all)	2 / 71 (2.82%) 2	0 / 71 (0.00%) 0	
Spinal compression fracture subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
Wound subjects affected / exposed occurrences (all)	2 / 71 (2.82%) 2	1 / 71 (1.41%) 1	
Wound complication subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
Cardiac disorders			
Angina pectoris subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	1 / 71 (1.41%) 1	
Arrhythmia subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	1 / 71 (1.41%) 1	
Atrial fibrillation subjects affected / exposed occurrences (all)	2 / 71 (2.82%) 2	1 / 71 (1.41%) 1	
Atrioventricular block first degree subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
Bradycardia subjects affected / exposed occurrences (all)	2 / 71 (2.82%) 2	1 / 71 (1.41%) 1	
Bundle branch block right subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
Tachycardia subjects affected / exposed occurrences (all)	2 / 71 (2.82%) 2	3 / 71 (4.23%) 3	
Nervous system disorders			
Dizziness			

subjects affected / exposed occurrences (all)	3 / 71 (4.23%) 3	5 / 71 (7.04%) 7	
Dysgeusia subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
Headache subjects affected / exposed occurrences (all)	5 / 71 (7.04%) 5	5 / 71 (7.04%) 6	
Hypoaesthesia subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
Hypotonia subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
Migraine with aura subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
Phantom limb syndrome subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
Syncope subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
<b>Blood and lymphatic system disorders</b>			
Anaemia subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	1 / 71 (1.41%) 1	
Bone marrow oedema subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
Leukocytopenia subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	1 / 71 (1.41%) 1	
Pancytopenia subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	1 / 71 (1.41%) 1	

Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	1 / 71 (1.41%) 1	
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
Eye disorders Blindness subjects affected / exposed occurrences (all)  Conjunctival haemorrhage subjects affected / exposed occurrences (all)  Vitreous haemorrhage subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0  0 / 71 (0.00%) 0  0 / 71 (0.00%) 0	2 / 71 (2.82%) 2  1 / 71 (1.41%) 1  1 / 71 (1.41%) 1	
Gastrointestinal disorders Abdominal discomfort subjects affected / exposed occurrences (all)  Abdominal pain subjects affected / exposed occurrences (all)  Abdominal pain upper subjects affected / exposed occurrences (all)  Diarrhoea subjects affected / exposed occurrences (all)  Dyspepsia subjects affected / exposed occurrences (all)  Nausea subjects affected / exposed occurrences (all)  Toothache	0 / 71 (0.00%) 0  2 / 71 (2.82%) 2  0 / 71 (0.00%) 0  10 / 71 (14.08%) 13  1 / 71 (1.41%) 1  6 / 71 (8.45%) 7	1 / 71 (1.41%) 1  2 / 71 (2.82%) 3  2 / 71 (2.82%) 2  9 / 71 (12.68%) 14  0 / 71 (0.00%) 0  5 / 71 (7.04%) 5	

subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	1 / 71 (1.41%) 1	
Vomiting subjects affected / exposed occurrences (all)	7 / 71 (9.86%) 10	7 / 71 (9.86%) 8	
<b>Skin and subcutaneous tissue disorders</b>			
<b>Eczema</b> subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
<b>Erythema</b> subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	1 / 71 (1.41%) 1	
<b>Hyperhidrosis</b> subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	1 / 71 (1.41%) 1	
<b>Pruritus</b> subjects affected / exposed occurrences (all)	3 / 71 (4.23%) 3	4 / 71 (5.63%) 4	
<b>Rash</b> subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	3 / 71 (4.23%) 3	
<b>Rash macular</b> subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	1 / 71 (1.41%) 1	
<b>Skin ulcer</b> subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
<b>Renal and urinary disorders</b>			
<b>Haematuria</b> subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
<b>Musculoskeletal and connective tissue disorders</b>			
<b>Arthralgia</b> subjects affected / exposed occurrences (all)	4 / 71 (5.63%) 5	3 / 71 (4.23%) 3	
<b>Back pain</b>			

subjects affected / exposed occurrences (all)	4 / 71 (5.63%) 5	3 / 71 (4.23%) 3	
Foot deformity subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
Groin pain subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
Joint swelling subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	1 / 71 (1.41%) 1	
Muscle spasms subjects affected / exposed occurrences (all)	5 / 71 (7.04%) 9	9 / 71 (12.68%) 14	
Musculoskeletal pain subjects affected / exposed occurrences (all)	3 / 71 (4.23%) 3	0 / 71 (0.00%) 0	
Myalgia subjects affected / exposed occurrences (all)	2 / 71 (2.82%) 2	0 / 71 (0.00%) 0	
Neck pain subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 2	0 / 71 (0.00%) 0	
Osteoarthritis subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
Pain in extremity subjects affected / exposed occurrences (all)	6 / 71 (8.45%) 6	8 / 71 (11.27%) 11	
<b>Infections and infestations</b>			
Abscess limb subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
Conjunctivitis subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	1 / 71 (1.41%) 1	

Device related infection		
subjects affected / exposed	4 / 71 (5.63%)	2 / 71 (2.82%)
occurrences (all)	5	2
Erysipelas		
subjects affected / exposed	2 / 71 (2.82%)	0 / 71 (0.00%)
occurrences (all)	3	0
Gangrene		
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	1	0
Infection		
subjects affected / exposed	2 / 71 (2.82%)	1 / 71 (1.41%)
occurrences (all)	2	1
Influenza		
subjects affected / exposed	5 / 71 (7.04%)	2 / 71 (2.82%)
occurrences (all)	6	3
Nasopharyngitis		
subjects affected / exposed	4 / 71 (5.63%)	4 / 71 (5.63%)
occurrences (all)	5	4
Osteomyelitis		
subjects affected / exposed	1 / 71 (1.41%)	1 / 71 (1.41%)
occurrences (all)	1	1
Pulpitis dental		
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	1	0
Respiratory tract infection		
subjects affected / exposed	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	1
Rhinitis		
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	1	0
Sinusitis fungal		
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	1	0
Staphylococcal infection		
subjects affected / exposed	3 / 71 (4.23%)	1 / 71 (1.41%)
occurrences (all)	3	1

Urinary tract infection subjects affected / exposed occurrences (all)	5 / 71 (7.04%) 9	1 / 71 (1.41%) 1	
Wound infection subjects affected / exposed occurrences (all)	0 / 71 (0.00%) 0	1 / 71 (1.41%) 1	
Metabolism and nutrition disorders			
Hypoglycaemia subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	
Decreased appetite subjects affected / exposed occurrences (all)	1 / 71 (1.41%) 1	0 / 71 (0.00%) 0	

## **More information**

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

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported