



Clinical trial results:

Phase 2/3 Open-label, Randomized, Active-controlled Clinical Study to Evaluate the Safety, Tolerability, Efficacy and Pharmacokinetics of MK-7655A in Pediatric Participants From Birth to Less Than 18 Years of Age With Confirmed or Suspected Gram-negative Bacterial Infection

Summary

EudraCT number	2019-000338-20
Trial protocol	FR PL Outside EU/EEA ES BG GR NO EE
Global end of trial date	07 May 2024

Results information

Result version number	v2 (current)
This version publication date	12 June 2025
First version publication date	24 January 2025
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	MK-7655A-021
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03969901
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme LLC
Sponsor organisation address	126 East Lincoln Avenue, P.O. Box 2000, Rahway, NJ, United States, 07065
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@merck.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-001809-PIP01-15
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	07 May 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 May 2024
Global end of trial reached?	Yes
Global end of trial date	07 May 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary purpose of this study is to evaluate the safety and tolerability of imipenem/cilastatin/relebactam (IMI/REL) in participants from birth to less than 18 years of age with confirmed or suspected gram-negative bacterial infection. Participants are expected to require hospitalization through completion of intravenous (IV) study intervention, and have at least one of the following primary infection types: hospital-acquired bacterial pneumonia (HABP) or ventilator-associated bacterial pneumonia (VABP); complicated intra-abdominal infection (cIAI); or complicated urinary tract infection (cUTI).

Participants will be randomized in a 3:1 ratio to receive IMI/REL or active control. This study will also evaluate the efficacy of IMI/REL by assessing all-cause mortality at Day 28 post-randomization, as well as clinical and microbiological response to treatment. It will also evaluate the pharmacokinetics of IMI/REL.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 October 2019
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	Bulgaria: 3
Country: Number of subjects enrolled	Chile: 3
Country: Number of subjects enrolled	Colombia: 12
Country: Number of subjects enrolled	Spain: 6
Country: Number of subjects enrolled	France: 2
Country: Number of subjects enrolled	Greece: 5
Country: Number of subjects enrolled	Israel: 4
Country: Number of subjects enrolled	Mexico: 20
Country: Number of subjects enrolled	Norway: 2
Country: Number of subjects enrolled	Poland: 7
Country: Number of subjects enrolled	Russian Federation: 17
Country: Number of subjects enrolled	Türkiye: 11
Country: Number of subjects enrolled	Ukraine: 14
Country: Number of subjects enrolled	United States: 7

Country: Number of subjects enrolled	South Africa: 2
Worldwide total number of subjects	115
EEA total number of subjects	25

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	3
Infants and toddlers (28 days-23 months)	28
Children (2-11 years)	72
Adolescents (12-17 years)	12
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

All 15 of the nonrandomized participants who were screened but not enrolled were screen failures who either did not meet inclusion criteria or met exclusion criteria.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Age 12 to <18 years - IMI/REL

Arm description:

Adolescents were administered IMI/REL via intravenous (IV) infusion once every 6 hours (Q6W)

Arm type	Experimental
Investigational medicinal product name	IMI/REL (imipenem/cilastatin/relebactam)
Investigational medicinal product code	
Other name	MK-7655A
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

IMI 500 and REL 250 mg, IV infusion every 6 hours (q6h)

Arm title	Age 12 to <18 years- active control
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Arm description:

Adolescents were administered acceptable control option for each infection type via intravenous (IV) infusion

Arm type	Active comparator
Investigational medicinal product name	Active Control
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

Acceptable control options for each infection type (HABP or VABP, cIAI, and UTI) and will be given via IV infusion, per authorized Package Insert (PI), Summary of Product Characteristics (SPC), or international treatment guidelines.

Arm title	Age 6 to <12 years - IMI/REL
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Arm description:

Older children were administered IMI/REL via intravenous (IV) infusion once every 6 hours (Q6W)

Arm type	Experimental
Investigational medicinal product name	IMI/REL (imipenem/cilastatin/relebactam)
Investigational medicinal product code	
Other name	MK-7655A
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

IMI 15 and REL 7.5 mg/kg, IV infusion every 6 hours (q6h)

Arm title	Age 6 to <12 years - active control
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Arm description:

Older children were administered acceptable control option for each infection type via intravenous (IV) infusion

Arm type	Active comparator
Investigational medicinal product name	Active Control
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

Acceptable control options for each infection type (HABP or VABP, cIAI, and UTI) and will be given via IV infusion, per authorized Package Insert (PI), Summary of Product Characteristics (SPC), or international treatment guidelines.

Arm title	Age 2 to <6 years - IMI/REL
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Arm description:

Young children were administered IMI/REL via intravenous (IV) infusion once every 6 hours (Q6W)

Arm type	Experimental
Investigational medicinal product name	IMI/REL (imipenem/cilastatin/relebactam)
Investigational medicinal product code	
Other name	MK-7655A
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

IMI 15 and REL 7.5 mg/kg, IV infusion every 6 hours (q6h)

Arm title	Age 2 to <6 years - active control
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Arm description:

Younger children were administered acceptable control option for each infection type via intravenous (IV) infusion

Arm type	Active comparator
Investigational medicinal product name	Active Control
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

Acceptable control options for each infection type (HABP or VABP, cIAI, and UTI) and will be given via IV infusion, per authorized Package Insert (PI), Summary of Product Characteristics (SPC), or international treatment guidelines.

Arm title	Age 3 months to <2 years - IMI/REL
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Arm description:

Infants and toddlers were administered IMI/REL via intravenous (IV) infusion once every 6 hours (Q6W)

Arm type	Experimental
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Investigational medicinal product name	IMI/REL (imipenem/cilastatin/relebactam)
Investigational medicinal product code	
Other name	MK-7655A
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intravenous use
Dosage and administration details:	
IMI 15 and REL 7.5 mg/kg, IV infusion every 6 hours (q6h)	
Arm title	Age 3 months to <2 years- Active Control

Arm description:

Infants and toddlers were administered acceptable control option for each infection type via intravenous (IV) infusion

Arm type	Active comparator
Investigational medicinal product name	Active Control
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

Acceptable control options for each infection type (HABP or VABP, cIAI, and UTI) and will be given via IV infusion, per authorized Package Insert (PI), Summary of Product Characteristics (SPC), or international treatment guidelines.

Arm title	Age Birth to <3 months: - IMI/REL
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Arm description:

Neonates and young infants were administered IMI/REL via intravenous (IV) infusion once every 8 hours (Q8W)

Arm type	Experimental
Investigational medicinal product name	IMI/REL (imipenem/cilastatin/relebactam)
Investigational medicinal product code	
Other name	MK-7655A
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

IMI 15 and REL 7.5 mg/kg, IV infusion every 8 hours (q8h)

Arm title	Age Birth to <3 months - active control
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Arm description:

Neonates and young infants were administered acceptable control option for each infection type via intravenous (IV) infusion

Arm type	Active comparator
Investigational medicinal product name	Active Control
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

Acceptable control options for each infection type (HABP or VABP, cIAI, and UTI) and will be given via IV infusion, per authorized Package Insert (PI), Summary of Product Characteristics (SPC), or international treatment guidelines.

Number of subjects in period 1	Age 12 to <18 years - IMI/REL	Age 12 to <18 years- active control	Age 6 to <12 years - IMI/REL
Started	10	2	31
Treated	10	2	31
Completed	10	2	31
Not completed	0	0	0
Withdrawal by parent/guardian	-	-	-

Number of subjects in period 1	Age 6 to <12 years - active control	Age 2 to <6 years - IMI/REL	Age 2 to <6 years - active control
Started	11	22	8
Treated	11	21	8
Completed	11	21	8
Not completed	0	1	0
Withdrawal by parent/guardian	-	1	-

Number of subjects in period 1	Age 3 months to <2 years - IMI/REL	Age 3 months to <2 years- Active Control	Age Birth to <3 months: - IMI/REL
Started	15	5	8
Treated	15	4	8
Completed	15	4	7
Not completed	0	1	1
Withdrawal by parent/guardian	-	1	1

Number of subjects in period 1	Age Birth to <3 months - active control
Started	3
Treated	3
Completed	3
Not completed	0
Withdrawal by parent/guardian	-

Baseline characteristics

Reporting groups

Reporting group title	Treatment
Reporting group description: -	

Reporting group values	Treatment	Total	
Number of subjects	115	115	
Age Categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	3	3	
Infants and toddlers (28 days-23 months)	28	28	
Children (2-11 years)	72	72	
Adolescents (12-17 years)	12	12	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Gender Categorical			
Units: Subjects			
Female	56	56	
Male	59	59	
Ethnicity			
NIH Categories for ethnicity			
Units: Subjects			
Hispanic or Latino	43	43	
Not Hispanic or Latino	70	70	
Unknown or Not Reported	2	2	
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	4	4	
Asian	1	1	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	4	4	
White	94	94	
Unknown or Not Reported	0	0	
More than one race	12	12	
Infection Type			
Infection type for this study indicates one of three types of infections: complicated intraabdominal infection (cIAI); complicated urinary tract infection (cUTI); or hospital acquired bacterial pneumonia/ventilator acquired bacterial pneumonia (HABP/VABP)			
Units: Subjects			
cIAI	54	54	
cUTI	55	55	
HABP/VABP	6	6	

Subject analysis sets

Subject analysis set title	All Participants Randomized- IMI/REL
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
all participants across age cohorts randomized to IMI/REL at baseline	
Subject analysis set title	All Participants Randomized- Active Control
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
All participants across age cohorts randomized to active control at baseline	

Reporting group values	All Participants Randomized- IMI/REL	All Participants Randomized- Active Control	
Number of subjects	86	29	
Age Categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	1	2	
Infants and toddlers (28 days-23 months)	22	6	
Children (2-11 years)	53	19	
Adolescents (12-17 years)	10	2	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Gender Categorical			
Units: Subjects			
Female	43	13	
Male	43	16	
Ethnicity			
NIH Categories for ethnicity			
Units: Subjects			
Hispanic or Latino	34	9	
Not Hispanic or Latino	50	20	
Unknown or Not Reported	2	0	
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	3	1	
Asian	0	1	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	3	1	
White	72	22	
Unknown or Not Reported	0	0	
More than one race	8	4	
Infection Type			
Infection type for this study indicates one of three types of infections: complicated intraabdominal infection (cIAI); complicated urinary tract infection (cUTI); or hospital acquired bacterial pneumonia/ventilator acquired bacterial pneumonia (HABP/VABP)			
Units: Subjects			

cIAI	40	14	
cUTI	41	14	
HABP/VABP	5	1	

End points

End points reporting groups

Reporting group title	Age 12 to <18 years - IMI/REL
Reporting group description: Adolescents were administered IMI/REL via intravenous (IV) infusion once every 6 hours (Q6W)	
Reporting group title	Age 12 to <18 years- active control
Reporting group description: Adolescents were administered acceptable control option for each infection type via intravenous (IV) infusion	
Reporting group title	Age 6 to <12 years - IMI/REL
Reporting group description: Older children were administered IMI/REL via intravenous (IV) infusion once every 6 hours (Q6W)	
Reporting group title	Age 6 to <12 years - active control
Reporting group description: Older children were administered acceptable control option for each infection type via intravenous (IV) infusion	
Reporting group title	Age 2 to <6 years - IMI/REL
Reporting group description: Young children were administered IMI/REL via intravenous (IV) infusion once every 6 hours (Q6W)	
Reporting group title	Age 2 to <6 years - active control
Reporting group description: Younger children were administered acceptable control option for each infection type via intravenous (IV) infusion	
Reporting group title	Age 3 months to <2 years - IMI/REL
Reporting group description: Infants and toddlers were administered IMI/REL via intravenous (IV) infusion once every 6 hours (Q6W)	
Reporting group title	Age 3 months to <2 years- Active Control
Reporting group description: Infants and toddlers were administered acceptable control option for each infection type via intravenous (IV) infusion	
Reporting group title	Age Birth to <3 months: - IMI/REL
Reporting group description: Neonates and young infants were administered IMI/REL via intravenous (IV) infusion once every 8 hours (Q8W)	
Reporting group title	Age Birth to <3 months - active control
Reporting group description: Neonates and young infants were administered acceptable control option for each infection type via intravenous (IV) infusion	
Subject analysis set title	All Participants Randomized- IMI/REL
Subject analysis set type	Intention-to-treat
Subject analysis set description: all participants across age cohorts randomized to IMI/REL at baseline	
Subject analysis set title	All Participants Randomized- Active Control
Subject analysis set type	Intention-to-treat
Subject analysis set description: All participants across age cohorts randomized to active control at baseline	

Primary: Percentage of Participants With One or More Adverse Events (AEs)

End point title	Percentage of Participants With One or More Adverse Events (AEs) ^[1]
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End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a study intervention. The percentage of participants with AEs is resented. The population analyzed includes all randomized participants who received at least one dose of IV study intervention.

End point type	Primary
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End point timeframe:

Up to approximately 28 days

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 official hypothesis testing was performed for this study.

End point values	Age 12 to <18 years - IMI/REL	Age 12 to <18 years- active control	Age 6 to <12 years - IMI/REL	Age 6 to <12 years - active control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	2	31	11
Units: Percentage				
number (not applicable)	60.0	50.0	64.5	36.4

End point values	Age 2 to <6 years - IMI/REL	Age 2 to <6 years - active control	Age 3 months to <2 years - IMI/REL	Age 3 months to <2 years- Active Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	8	15	4
Units: Percentage				
number (not applicable)	71.4	62.5	93.3	50.0

End point values	Age Birth to <3 months: - IMI/REL	Age Birth to <3 months - active control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	2		
Units: Percentage				
number (not applicable)	25.0	66.7		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Who Discontinued Study Medication Due to an Adverse Event (AE)

End point title	Percentage of Participants Who Discontinued Study Medication Due to an Adverse Event (AE) ^[2]
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End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a study intervention. The percentage of participants with AEs is resented. The population analyzed includes all randomized participants who received at least one dose of IV study intervention.

End point type	Primary
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End point timeframe:

Up to approximately 14 days

Notes:

[2] - 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 official hypothesis testing was performed for this study.

End point values	Age 12 to <18 years - IMI/REL	Age 12 to <18 years- active control	Age 6 to <12 years - IMI/REL	Age 6 to <12 years - active control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	2	31	11
Units: Subjects				
number (not applicable)	0.0	0.0	12.9	9.1

End point values	Age 2 to <6 years - IMI/REL	Age 2 to <6 years - active control	Age 3 months to <2 years - IMI/REL	Age 3 months to <2 years- Active Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	8	14	4
Units: Subjects				
number (not applicable)	0.0	0.0	6.74	25.0

End point values	Age Birth to <3 months: - IMI/REL	Age Birth to <3 months - active control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	3		
Units: Subjects				
number (not applicable)	0.0	0.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Deaths by All Causes Through Day 28

End point title	Number of Deaths by All Causes Through Day 28
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End point description:

All-cause mortality up to 28 days post-randomization is presented. The population analyzed includes all randomized participants who received at least 1 dose of IV study intervention.

End point type	Secondary
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End point timeframe:

Up to Day 28

End point values	All Participants Randomized-IMI/REL	All Participants Randomized-Active Control		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	85	28		
Units: Participants	0	0		

Statistical analyses

Statistical analysis title	Difference in Incidence of All-Cause Mortality
Comparison groups	All Participants Randomized- Active Control v All Participants Randomized- IMI/REL
Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percent vs Active Control
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.2
upper limit	4.4

Secondary: Percentage of Participants With a Favorable Clinical Response at End of Therapy (EOT)

End point title	Percentage of Participants With a Favorable Clinical Response at End of Therapy (EOT)
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End point description:

A favorable clinical response is defined as either "Cure"-All preintervention signs and symptoms of the index infection have resolved (or returned to "preinfection status", with no new symptoms) AND no additional antibacterial intervention is required for the index infection, or "Improved" - The majority of preintervention signs and symptoms of the index infection have improved or resolved (or returned to "preinfection status", with no new symptoms) AND no additional antibacterial intervention is required. The population analyzed includes all randomized participants who received at least 1 dose of IV study intervention.

End point type	Secondary
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End point timeframe:

Day 5 up to Day 14

End point values	Age 12 to <18 years - IMI/REL	Age 12 to <18 years- active control	Age 6 to <12 years - IMI/REL	Age 6 to <12 years - active control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	2	31	11
Units: Percentage of Participants				
number (confidence interval 95%)	90 (57.4 to 100.0)	50.0 (9.5 to 90.5)	77.4 (59.9 to 88.9)	81.8 (51.2 to 96.0)

End point values	Age 2 to <6 years - IMI/REL	Age 2 to <6 years - active control	Age 3 months to <2 years - IMI/REL	Age 3 months to <2 years- Active Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	8	15	4
Units: Percentage of Participants				
number (confidence interval 95%)	90.5 (69.9 to 98.6)	87.5 (50.8 to 99.9)	53.3 (30.1 to 75.2)	75.0 (28.9 to 96.6)

End point values	Age Birth to <3 months: - IMI/REL	Age Birth to <3 months - active control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	3		
Units: Percentage of Participants				
number (confidence interval 95%)	87.5 (50.8 to 99.9)	33.3 (5.6 to 79.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Favorable Clinical Response at Early Follow-Up (EFU)

End point title	Percentage of Participants with Favorable Clinical Response at Early Follow-Up (EFU)
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End point description:

A favorable clinical response at EFU requires an assessment of "Sustained Cure" -All preintervention signs and symptoms of the index infection have resolved (or returned to "preinfection status", with no new symptoms) with no evidence of resurgence AND no additional antibacterial intervention is required for the index infection, or "Cure" - All preintervention signs and symptoms of the index infection have resolved (or returned to "preinfection status", with no new symptoms) AND no additional antibacterial intervention is required for the index infection.

End point type	Secondary
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End point timeframe:

Day 12 up to Day 28

End point values	Age 12 to <18 years - IMI/REL	Age 12 to <18 years- active control	Age 6 to <12 years - IMI/REL	Age 6 to <12 years - active control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	2	31	11
Units: Percentage of Participants				
number (confidence interval 95%)	90.0 (57.4 to 100.0)	50.0 (9.5 to 90.5)	77.4 (59.9 to 88.9)	81.8 (51.2 to 96.0)

End point values	Age 2 to <6 years - IMI/REL	Age 2 to <6 years - active control	Age 3 months to <2 years - IMI/REL	Age 3 months to <2 years- Active Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	8	15	4
Units: Percentage of Participants				
number (confidence interval 95%)	85.7 (64.5 to 95.9)	87.5 (50.8 to 99.9)	26.7 (10.5 to 52.4)	75.0 (28.9 to 96.6)

End point values	Age Birth to <3 months: - IMI/REL	Age Birth to <3 months - active control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	3		
Units: Percentage of Participants				
number (confidence interval 95%)	62.5 (30.4 to 86.5)	33.3 (5.6 to 79.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Favorable Clinical Response at Late Follow-Up (LFU)

End point title	Percentage of Participants With a Favorable Clinical Response at Late Follow-Up (LFU)
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End point description:

A favorable clinical response at EFU requires an assessment of "Sustained Cure" -All preintervention signs and symptoms of the index infection have resolved (or returned to "preinfection status", with no new symptoms) with no evidence of resurgence AND no additional antibacterial intervention is required for the index infection, or "Cure" - All preintervention signs and symptoms of the index infection have resolved (or returned to "preinfection status", with no new symptoms) AND no additional antibacterial intervention is required for the index infection.

End point type	Secondary
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End point timeframe:

Day 19 up to Day 42

End point values	Age 12 to <18 years - IMI/REL	Age 12 to <18 years- active control	Age 6 to <12 years - IMI/REL	Age 6 to <12 years - active control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	2	31	11
Units: Percentage of Participants				
number (confidence interval 95%)	90.0 (57.4 to 100.0)	50.0 (9.5 to 90.5)	74.2 (56.5 to 86.5)	81.8 (51.2 to 96.0)

End point values	Age 2 to <6 years - IMI/REL	Age 2 to <6 years - active control	Age 3 months to <2 years - IMI/REL	Age 3 months to <2 years- Active Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	8	15	4
Units: Percentage of Participants				
number (confidence interval 95%)	81.0 (59.4 to 92.9)	87.5 (50.8 to 99.9)	33.3 (15.0 to 58.5)	75.0 (28.9 to 96.6)

End point values	Age Birth to <3 months: - IMI/REL	Age Birth to <3 months - active control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	3		
Units: Percentage of Participants				
number (confidence interval 95%)	62.5 (30.4 to 86.5)	33.3 (5.6 to 79.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Favorable Microbiological Response at End of Therapy (EOT)

End point title	Percentage of Participants With a Favorable Microbiological Response at End of Therapy (EOT)
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End point description:

A favorable by-pathogen microbiological response at EOT requires “eradication” or “presumed eradication” of the pathogen found at study entry. The population analyzed included all randomized participants who met the following conditions:

For participants with HABP/VABP and cIAI: The participant received at least 1 dose of IV study intervention; AND The participant’s baseline infection-site culture grew at least 1 gram-negative pathogenic organism.

For participants with cUTI: The participant received at least 1 dose of IV study intervention; AND The participant’s baseline urine culture grew at least 1 gram-negative pathogenic organism at sufficient quantity (ie, growth at $\geq 10^5$ CFU/mL of uropathogen). Participants were included in the intervention group to which they were randomized.

End point type	Secondary
End point timeframe:	
Day 5 up to Day 14	

End point values	Age 12 to <18 years - IMI/REL	Age 12 to <18 years - active control	Age 6 to <12 years - IMI/REL	Age 6 to <12 years - active control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	2	27	10
Units: Percentage of Participants				
number (confidence interval 95%)	100.0 (59.6 to 100.0)	100.0 (16.7 to 100.0)	100.0 (85.2 to 100.0)	100.0 (67.9 to 100.0)

End point values	Age 2 to <6 years - IMI/REL	Age 2 to <6 years - active control	Age 3 months to <2 years - IMI/REL	Age 3 months to <2 years - Active Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	5	11	4
Units: Percentage of Participants				
number (confidence interval 95%)	100.0 (77.3 to 100.0)	100.0 (51.1 to 100.0)	72.7 (42.9 to 90.8)	75.0 (28.9 to 96.6)

End point values	Age Birth to <3 months: - IMI/REL	Age Birth to <3 months - active control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	2		
Units: Percentage of Participants				
number (confidence interval 95%)	100.0 (59.6 to 100.0)	50.0 (9.5 to 90.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Favorable Microbiological Response at End of Follow-Up (EFU)

End point title	Percentage of Participants With a Favorable Microbiological Response at End of Follow-Up (EFU)
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End point description:

A favorable by-pathogen microbiological response at the EFU visit requires "eradication" or "presumed eradication" of the pathogen found at study entry. The population analyzed included all randomized participants who met the following conditions:

For participants with HABP/VABP and cIAI: The participant received at least 1 dose of IV study intervention; AND The participant's baseline infection-site culture grew at least 1 gram-negative pathogenic organism.

For participants with cUTI: The participant received at least 1 dose of IV study intervention; AND The participant's baseline urine culture grew at least 1 gram-negative pathogenic organism at sufficient quantity (ie, growth at $\geq 10^5$ CFU/mL of uropathogen). Participants were included in the intervention group to which they were randomized.

End point type	Secondary
End point timeframe:	
Day 12 up to Day 28	

End point values	Age 12 to <18 years - IMI/REL	Age 12 to <18 years - active control	Age 6 to <12 years - IMI/REL	Age 6 to <12 years - active control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	1	27	10
Units: Percentage of Participants				
number (confidence interval 95%)	71.4 (35.2 to 92.4)	100.0 (16.7 to 100.0)	96.3 (80.2 to 100.0)	100.0 (67.9 to 100.0)

End point values	Age 2 to <6 years - IMI/REL	Age 2 to <6 years - active control	Age 3 months to <2 years - IMI/REL	Age 3 months to <2 years - Active Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	5	11	4
Units: Percentage of Participants				
number (confidence interval 95%)	93.8 (69.7 to 100.0)	100.0 (51.1 to 100.0)	63.6 (35.2 to 85.0)	75.0 (28.9 to 96.6)

End point values	Age Birth to <3 months: - IMI/REL	Age Birth to <3 months - active control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	2		
Units: Percentage of Participants				
number (confidence interval 95%)	71.4 (35.2 to 92.4)	50.0 (9.5 to 90.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Favorable Microbiological Response at Late Follow-Up (LFU)

End point title	Percentage of Participants With a Favorable Microbiological Response at Late Follow-Up (LFU)
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End point description:

A favorable by-pathogen microbiological response at the EFU visit requires "eradication" or "presumed eradication" of the pathogen found at study entry. The population analyzed included all randomized

participants who met the following conditions:

For participants with HABP/VABP and cIAI: The participant received at least 1 dose of IV study intervention; AND The participant's baseline infection-site culture grew at least 1 gram-negative pathogenic organism.

For participants with cUTI: The participant received at least 1 dose of IV study intervention; AND The participant's baseline urine culture grew at least 1 gram-negative pathogenic organism at sufficient quantity (ie, growth at $\geq 10^5$ CFU/mL of uropathogen). Participants were included in the intervention group to which they were randomized.

End point type	Secondary
End point timeframe:	
Day 19 up to Day 42	

End point values	Age 12 to <18 years - IMI/REL	Age 12 to <18 years- active control	Age 6 to <12 years - IMI/REL	Age 6 to <12 years - active control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	1	27	10
Units: Percentage of Participants				
number (confidence interval 95%)	85.7 (46.7 to 99.5)	0.0 (0.0 to 83.3)	96.3 (80.2 to 100.0)	100.0 (67.9 to 100.0)

End point values	Age 2 to <6 years - IMI/REL	Age 2 to <6 years - active control	Age 3 months to <2 years - IMI/REL	Age 3 months to <2 years- Active Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	5	11	4
Units: Percentage of Participants				
number (confidence interval 95%)	87.5 (62.7 to 97.8)	100.0 (51.1 to 100.0)	72.7 (42.9 to 90.8)	75.0 (28.9 to 96.6)

End point values	Age Birth to <3 months: - IMI/REL	Age Birth to <3 months - active control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	2		
Units: Percentage of Participants				
number (confidence interval 95%)	71.4 (35.2 to 92.4)	50.0 (9.5 to 90.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Curve From Time 0 to 24 Hours (AUC0-24) of Imipenem Following Administration of IMI/REL

End point title	Area Under the Curve From Time 0 to 24 Hours (AUC0-24) of
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End point description:

Blood samples were collected to determine the AUC₀₋₂₄ of Imipenem. The population analyzed includes all participants who received at least 1 dose of IMI/REL and had at least one measurable pharmacokinetic (PK) sample.

End point type	Secondary
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End point timeframe:

On Day 1 at 30 minutes prior to start of first IV infusion of study drug, at end of first infusion, and 2 to 6 hours after start of first infusion; and once at on-therapy visit (Day 2 or Day 3) at 2 to 6 hours after start of any infusion that day.

Notes:

[3] - 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: No official hypothesis testing was performed for this study.

End point values	Age 12 to <18 years - IMI/REL	Age 6 to <12 years - IMI/REL	Age 2 to <6 years - IMI/REL	Age 3 months to <2 years - IMI/REL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	31	21	15
Units: µM/hr				
geometric mean (geometric coefficient of variation)	610 (± 55.5)	720 (± 25.8)	692 (± 23.5)	788 (± 28.4)

End point values	Age Birth to <3 months: - IMI/REL			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: µM/hr				
geometric mean (geometric coefficient of variation)	795 (± 19.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: AUC₀₋₂₄ of Relebactam Following Administration of IMI/REL

End point title	AUC ₀₋₂₄ of Relebactam Following Administration of IMI/REL ^[4]
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End point description:

Blood samples were collected to determine the AUC₀₋₂₄ of relebactam. The population analyzed includes all participants who received at least 1 dose of IMI/REL and had at least one measurable pharmacokinetic (PK) sample.

End point type	Secondary
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End point timeframe:

On Day 1 at 30 minutes prior to start of first IV infusion of study drug, at end of first infusion, and 2 to 6 hours after start of first infusion; and once at on-therapy visit (Day 2 or Day 3) at 2 to 6 hours after start of any infusion that day.

Notes:

[4] - 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: No official hypothesis testing was performed for this study.

End point values	Age 12 to <18 years - IMI/REL	Age 6 to <12 years - IMI/REL	Age 2 to <6 years - IMI/REL	Age 3 months to <2 years - IMI/REL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	31	21	15
Units: µM/hr				
geometric mean (geometric coefficient of variation)	399 (± 64)	469 (± 30.9)	459 (± 30.4)	634 (± 56.8)

End point values	Age Birth to <3 months: - IMI/REL			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: µM/hr				
geometric mean (geometric coefficient of variation)	605 (± 50.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration at End of Infusion (Ceoi) of Imipenem Following Administration of IMI/REL

End point title	Concentration at End of Infusion (Ceoi) of Imipenem Following Administration of IMI/REL ^[5]
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End point description:

Blood samples were collected to determine the Ceoi of imipenem. The population analyzed includes all participants who received at least 1 dose of IMI/REL and had at least one measurable pharmacokinetic (PK) sample.

End point type	Secondary
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End point timeframe:

At the end of the first infusion on Day 1

Notes:

[5] - 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: No official hypothesis testing was performed for this study.

End point values	Age 12 to <18 years - IMI/REL	Age 6 to <12 years - IMI/REL	Age 2 to <6 years - IMI/REL	Age 3 months to <2 years - IMI/REL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	31	21	15
Units: µM				
geometric mean (geometric coefficient of variation)	79.2 (± 17.6)	103 (± 15)	101 (± 12.7)	109 (± 14.1)

End point values	Age Birth to <3 months: - IMI/REL			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: µM				
geometric mean (geometric coefficient of variation)	117 (± 5.51)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Free Time Imipenem Concentration Is Above Minimum Inhibitory Concentration (%fT>MIC) of Imipenem Following Administration of IMI/REL

End point title	Percentage of Free Time Imipenem Concentration Is Above Minimum Inhibitory Concentration (%fT>MIC) of Imipenem Following Administration of IMI/REL ^[6]
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End point description:

Blood samples were collected to determine the %fT>MIC of Imipenem. The population analyzed includes all participants who received at least 1 dose of IMI/REL, had at least one measurable PK sample, and had a baseline microbiological response.

End point type	Secondary
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End point timeframe:

On Day 1 at 30 minutes prior to start of first IV infusion of study drug, at end of first infusion, 2 to 6 hours after start of first infusion; and once at on-therapy visit (Day 2 or 3) at 2 to 6 hours after start of any infusion that day.

Notes:

[6] - 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: No official hypothesis testing was performed for this study.

End point values	Age 12 to <18 years - IMI/REL	Age 6 to <12 years - IMI/REL	Age 2 to <6 years - IMI/REL	Age 3 months to <2 years - IMI/REL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	22	15	8
Units: Percentage of Time				
arithmetic mean (standard deviation)	100 (± 0)	93.4 (± 22.1)	83.6 (± 23.1)	79.6 (± 35.3)

End point values	Age Birth to <3 months: - IMI/REL			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Percentage of Time				
arithmetic mean (standard deviation)	83.5 (± 25.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Ceoi of Relabactam Following Administration of IMI/REL

End point title	Ceoi of Relabactam Following Administration of IMI/REL ^[7]
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End point description:

Blood samples were collected to determine the Ceoi of relabactam . The population analyzed includes all participants who received at least 1 dose of IMI/REL and had at least one measurable pharmacokinetic (PK) sample.

End point type	Secondary
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End point timeframe:

At the end of the first infusion on Day 1.

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: No official hypothesis testing was performed for this study.

End point values	Age 12 to <18 years - IMI/REL	Age 6 to <12 years - IMI/REL	Age 2 to <6 years - IMI/REL	Age 3 months to <2 years - IMI/REL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	31	21	10
Units: µM				
geometric mean (geometric coefficient of variation)	43.4 (± 28.6)	56.1 (± 18.6)	56.1 (± 16.2)	67.1 (± 27.4)

End point values	Age Birth to <3 months: - IMI/REL			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: µM				
geometric mean (geometric coefficient of variation)	67.9 (± 22.2)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to approximately 42 days

Adverse event reporting additional description:

The populations analyzed includes all randomized participants who received at least 1 dose of study intervention. Participants were included in the intervention group corresponding to the study intervention they actually received.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.0
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Reporting groups

Reporting group title	Age 12 to <18 years - IMI/REL
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Reporting group description:

Adolescents were administered IMI/REL via intravenous (IV) infusion once every 6 hours (Q6W)

Reporting group title	Age 12 to <18 years – active control
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Reporting group description:

Adolescents were administered acceptable control option for each infection type via intravenous (IV) infusion

Reporting group title	6 to <12 years - IMI/REL
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Reporting group description:

Older children were administered IMI/REL via iIV infusion Q6W

Reporting group title	Age 6 to <12 years - active control
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Reporting group description:

Older children were administered acceptable control option for each infection type via IV infusion

Reporting group title	Age 2 to <6 years - IMI/REL
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Reporting group description:

Young children were administered IMI/REL via IV infusion Q6W

Reporting group title	Age 2 to <6 years - active control
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Reporting group description:

Younger children were administered acceptable control option for each infection type via iIV infusion

Reporting group title	Age 3 months to <2 years- IMI/REL
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Reporting group description:

Infants and toddlers were administered IMI/REL via IV infusion Q6W

Reporting group title	Age 3 months to <2 years - active control
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Reporting group description:

Infants and toddlers were administered acceptable control option for each infection type via iIV infusion

Reporting group title	Age Birth to <3 months - IMI/REL
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Reporting group description:

Neonates and young infants were administered IMI/REL via IV infusion Q8W

Reporting group title	Birth to <3 months - active control
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Reporting group description:

Neonates and young infants were administered acceptable control option for each infection type via IV infusion

Serious adverse events	Age 12 to <18 years - IMI/REL	Age 12 to <18 years - active control	6 to <12 years - IMI/REL
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	6 / 31 (19.35%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
General disorders and administration site conditions			
Drug intolerance			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Food poisoning			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	2 / 31 (6.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Short-bowel syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Escherichia urinary tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			

subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Age 6 to <12 years - active control	Age 2 to <6 years - IMI/REL	Age 2 to <6 years - active control
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 11 (9.09%)	0 / 21 (0.00%)	0 / 8 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
General disorders and administration site conditions			
Drug intolerance			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Food poisoning			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			

subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Short-bowel syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Escherichia urinary tract infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Age 3 months to <2 years- IMI/REL	Age 3 months to <2 years - active control	Age Birth to <3 months - IMI/REL
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 15 (26.67%)	1 / 4 (25.00%)	0 / 8 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
General disorders and administration site conditions			
Drug intolerance			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Food poisoning			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Short-bowel syndrome			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Escherichia urinary tract infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			

subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	2 / 15 (13.33%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Birth to <3 months - active control		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
General disorders and administration site conditions			
Drug intolerance			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Food poisoning			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Short-bowel syndrome			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Escherichia urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal infection			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Age 12 to <18 years - IMI/REL	Age 12 to <18 years - active control	6 to <12 years - IMI/REL
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 10 (60.00%)	1 / 2 (50.00%)	17 / 31 (54.84%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Drug withdrawal syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Infusion site extravasation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Infusion site phlebitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 2 (50.00%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Medical device site dermatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	2 / 31 (6.45%)
occurrences (all)	2	0	2
Thirst			

subjects affected / exposed	1 / 10 (10.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Vascular device occlusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Laryngospasm			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	3 / 31 (9.68%)
occurrences (all)	0	0	3
Urobilinogen urine increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Urine uric acid increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Creatinine urine decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Weight decreased			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
pH urine increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Bradycardia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	3 / 10 (30.00%) 3	0 / 2 (0.00%) 0	2 / 31 (6.45%) 2
Blood and lymphatic system disorders Neutropenia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Normochromic normocytic anaemia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Anaemia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Leukopenia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Thrombocytosis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	2 / 31 (6.45%) 2
Eye disorders			

Vision blurred subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	4 / 31 (12.90%) 4
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 2	0 / 2 (0.00%) 0	5 / 31 (16.13%) 15
Ileus subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	4 / 31 (12.90%) 4
Abdominal pain upper subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2	0 / 2 (0.00%) 0	5 / 31 (16.13%) 5
Skin and subcutaneous tissue disorders			
Decubitus ulcer subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Dermatitis diaper subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Rash maculo-papular			

subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Hyperhidrosis subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Renal and urinary disorders Urethral fistula subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Chromaturia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Musculoskeletal and connective tissue disorders Osteochondritis subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Joint swelling subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Infections and infestations Asymptomatic bacteriuria subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Device related infection subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Oral herpes subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 2 (0.00%) 0	0 / 31 (0.00%) 0
Otitis media			

subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Postoperative wound infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Hypervolaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 2 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Age 6 to <12 years - active control	Age 2 to <6 years - IMI/REL	Age 2 to <6 years - active control
Total subjects affected by non-serious adverse events			

subjects affected / exposed	3 / 11 (27.27%)	13 / 21 (61.90%)	5 / 8 (62.50%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 11 (0.00%)	2 / 21 (9.52%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Drug withdrawal syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Infusion site extravasation			
subjects affected / exposed	1 / 11 (9.09%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Infusion site phlebitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 21 (4.76%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Medical device site dermatitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 11 (0.00%)	1 / 21 (4.76%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 21 (4.76%)	1 / 8 (12.50%)
occurrences (all)	1	1	2
Thirst			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vascular device occlusion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Laryngospasm			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urobilinogen urine increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 21 (4.76%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Urine uric acid increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Creatinine urine decreased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
pH urine increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 21 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Tachycardia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	2 / 8 (25.00%) 2
Bradycardia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Blood and lymphatic system disorders Neutropenia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	2 / 21 (9.52%) 2	0 / 8 (0.00%) 0
Normochromic normocytic anaemia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Anaemia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 21 (4.76%) 1	0 / 8 (0.00%) 0
Leukopenia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	2 / 21 (9.52%) 2	0 / 8 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Thrombocytosis subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	2 / 21 (9.52%) 2	0 / 8 (0.00%) 0
Eye disorders Vision blurred subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 21 (4.76%) 1	1 / 8 (12.50%) 1

Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	1 / 8 (12.50%) 1
Nausea subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 21 (0.00%) 0	1 / 8 (12.50%) 1
Ileus subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	2 / 21 (9.52%) 2	0 / 8 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	3 / 21 (14.29%) 3	1 / 8 (12.50%) 1
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 21 (4.76%) 1	0 / 8 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	4 / 21 (19.05%) 5	3 / 8 (37.50%) 5
Skin and subcutaneous tissue disorders			
Decubitus ulcer subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	1 / 8 (12.50%) 1
Dermatitis diaper subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 21 (4.76%) 1	0 / 8 (0.00%) 0
Rash maculo-papular subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Renal and urinary disorders			

Urethral fistula subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Chromaturia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Osteochondritis subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Joint swelling subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	2 / 21 (9.52%) 2	0 / 8 (0.00%) 0
Infections and infestations			
Asymptomatic bacteriuria subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Device related infection subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	1 / 8 (12.50%) 1
Oral herpes subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Otitis media subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Otitis media acute subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 21 (4.76%) 1	0 / 8 (0.00%) 0
Viral infection			

subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Rhinitis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Respiratory tract infection subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Pyuria subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Postoperative wound infection subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	1 / 8 (12.50%) 1
Hypervolaemia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	0 / 8 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 21 (0.00%) 0	1 / 8 (12.50%) 1

Non-serious adverse events	Age 3 months to <2 years- IMI/REL	Age 3 months to <2 years - active control	Age Birth to <3 months - IMI/REL
Total subjects affected by non-serious adverse events subjects affected / exposed	12 / 15 (80.00%)	2 / 4 (50.00%)	2 / 8 (25.00%)
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
General disorders and administration site conditions			

Drug withdrawal syndrome subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Infusion site extravasation subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Infusion site phlebitis subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Medical device site dermatitis subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Oedema subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Pain subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Peripheral swelling subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Thirst subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Vascular device occlusion subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Reproductive system and breast disorders Balanoposthitis subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			

Atelectasis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Laryngospasm			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urobilinogen urine increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Urine uric acid increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Creatinine urine decreased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
pH urine increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Nervous system disorders			

Headache subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Blood and lymphatic system disorders			
Neutropenia subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Normochromic normocytic anaemia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Anaemia subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Leukopenia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 4 (25.00%) 1	0 / 8 (0.00%) 0
Thrombocytosis subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Eye disorders			
Vision blurred subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Ileus			

subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 2	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1
Skin and subcutaneous tissue disorders			
Decubitus ulcer subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Dermatitis diaper subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Rash maculo-papular subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Renal and urinary disorders			
Urethral fistula subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1
Chromaturia subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 2	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Musculoskeletal and connective tissue disorders			

Osteochondritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Device related infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Otitis media acute			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Viral infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Rhinitis			

subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Respiratory tract infection subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Pyuria subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Postoperative wound infection subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Hypervolaemia subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 2	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0

Non-serious adverse events	Birth to <3 months - active control		
Total subjects affected by non-serious adverse events subjects affected / exposed	1 / 3 (33.33%)		
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
General disorders and administration site conditions Drug withdrawal syndrome subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Infusion site extravasation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		

Infusion site phlebitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Medical device site dermatitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Oedema subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Peripheral swelling subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Pyrexia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Thirst subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Vascular device occlusion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Reproductive system and breast disorders Balanoposthitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Atelectasis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Laryngospasm subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Investigations			

Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Urobilinogen urine increased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Urine uric acid increased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Creatinine urine decreased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
pH urine increased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Bradycardia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		

Normochromic normocytic anaemia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Anaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Leukopenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Thrombocytosis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Eye disorders Vision blurred subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Nausea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Ileus subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Diarrhoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Abdominal pain upper			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Dermatitis diaper			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Urethral fistula			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Chromaturia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Osteochondritis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Pain in extremity			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Otitis media			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Otitis media acute			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Pyuria			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		

Postoperative wound infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Hypervolaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Dehydration subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 November 2019	Amendment 02: Decreased the planned enrollment numbers (including overall, by age group, and by infection site).
11 January 2022	Amendment 03: Clarified the dosing regimen of MK-7655A for participants enrolled in Age Cohorts 3 months to <2 years, and neonates and young infants, based on the interim review of safety, tolerability, and pharmacokinetic data. The amendment also added piperacillin/tazobactam IV to the list of comparator medications allowed for participants with complicated intra-abdominal infection (cIAI).
03 November 2022	Amendment 04: Sponsor entity name and address change
13 September 2023	Amendment 05: Clarified the type of infection required for enrollment of participants aged birth to <3 months in the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported