



Clinical trial results:

Pharmacokinetics of fosfomycin: a study in patients with prolonged treatment for urinary tract infection

Summary

EudraCT number	2018-000616-25
Trial protocol	NL
Global end of trial date	01 January 2020

Results information

Result version number	v1 (current)
This version publication date	25 December 2021
First version publication date	25 December 2021

Trial information

Trial identification

Sponsor protocol code	T17-084
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Haga Teaching Hospital
Sponsor organisation address	Els Borst-Eijlersplein 245, The Hague, Netherlands,
Public contact	S.G. Kuiper, Haga Teaching Hospital, s.g.kuiper@lumc.nl
Scientific contact	S.G. Kuiper, Haga Teaching Hospital, s.g.kuiper@lumc.nl

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	07 February 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 October 2019
Global end of trial reached?	Yes
Global end of trial date	01 January 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the pharmacokinetics of fosfomycine in patients with prolonged fosfomycin therapy to treat urinary tract infection

Protection of trial subjects:

none

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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)	5
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment was done from July 2019 till September 2019 in Haga Teaching Hospital, The Hague, The Netherlands

Pre-assignment

Screening details:

15 patients were screened and 12 were included in the trial.

Period 1

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

Arms

Arm title	Fosfomycin
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Fosfomycin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for oral solution in sachet
Routes of administration	Oral use

Dosage and administration details:

3 gram once

Investigational medicinal product name	Fosfomycin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

3 gram intravenous

Number of subjects in period 1	Fosfomycin
Started	12
Completed	12

Baseline characteristics

Reporting groups

Reporting group title	Overall trial
Reporting group description: -	

Reporting group values	Overall trial	Total	
Number of subjects	12	12	
Age categorical			
Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Units: years			
median	66		
full range (min-max)	44 to 76	-	
Gender categorical			
Units: Subjects			
Female	9	9	
Male	3	3	
BMI			
Units: kg/m2			
median	26.8		
full range (min-max)	20.4 to 28.7	-	
Renal function (eGFR)			
Units: ml/min/1.73 m2			
median	83		
full range (min-max)	63 to 103	-	

End points

End points reporting groups

Reporting group title	Fosfomycin
Reporting group description: -	

Primary: Fosfomycin serum concentrations

End point title	Fosfomycin serum concentrations ^[1]
End point description:	

End point type	Primary
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End point timeframe:

-

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 statistical analysis is done.

End point values	Fosfomycin			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mg/L				
number (not applicable)	12			

Attachments (see zip file)	20200120.IndividualPlotsLog.Model60.png
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Statistical analyses

No statistical analyses for this end point

Primary: Pharmacokinetic parameters

End point title	Pharmacokinetic parameters ^[2]
End point description:	

End point type	Primary
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End point timeframe:

-

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 statistical analysis is done.

End point values	Fosfomycin			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: parameter estimate	12			

Attachments (see zip file)	Figuur 2 2020-01-20- Predictions - VPC_Jasper.png
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Statistical analyses

No statistical analyses for this end point

Primary: Urine fosfomycin concentration at day 1

End point title	Urine fosfomycin concentration at day 1 ^[3]
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End point description:

End point type	Primary
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End point timeframe:

-

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis is done.

End point values	Fosfomycin			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mg/L				
geometric mean (standard deviation)	622.3 (± 335.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Urine fosfomycine concentration at day 2

End point title	Urine fosfomycine concentration at day 2 ^[4]
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End point description:

End point type	Primary
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End point timeframe:

-

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis is done.

End point values	Fosfomycin			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mg/L				
geometric mean (standard deviation)	41.4 (± 17.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Urine fosfomycin concentration at day 3

End point title	Urine fosfomycin concentration at day 3 ^[5]
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End point description:

End point type	Primary
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End point timeframe:

-

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis is done.

End point values	Fosfomycin			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mg/L				
geometric mean (standard deviation)	20.5 (± 45.6)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

1 month

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.1
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Reporting groups

Reporting group title	Fosfomycin
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Reporting group description: -

Serious adverse events	Fosfomycin		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	Fosfomycin		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 12 (66.67%)		
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 12 (58.33%)		
occurrences (all)	7		
General disorders and administration site conditions			
Tiredness			
subjects affected / exposed	8 / 12 (66.67%)		
occurrences (all)	8		
Gastrointestinal disorders			
Gastro-intestinal complaints			
subjects affected / exposed	8 / 12 (66.67%)		
occurrences (all)	8		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported