



Clinical trial results:

Impact of Model-Informed Precision Dosing of Vancomycin in Adults: A randomized, controlled clinical trial

Summary

EudraCT number	2021-003670-31
Trial protocol	BE
Global end of trial date	07 November 2023

Results information

Result version number	v1 (current)
This version publication date	29 May 2026
First version publication date	29 May 2026
Summary attachment (see zip file)	Final Study Report (2021-003670-31_MIPD_Final_Study_Report.pdf)

Trial information

Trial identification

Sponsor protocol code	BC-10433
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University Hospital Ghent
Sponsor organisation address	C. Heymanslaan 10, Gent, Belgium, 9000
Public contact	HIRUZ, Ghent University Hospital, +32 093320530, hiruz.ctu@uzgent.be
Scientific contact	HIRUZ, Ghent University Hospital, +32 093320530, hiruz.ctu@uzgent.be

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	12 May 2026
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 November 2023
Global end of trial reached?	Yes
Global end of trial date	07 November 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study will test the primary hypothesis that AUC/MIC based vancomycin dosing, using a model-informed precision dosing calculator, increases the proportion of patients reaching the therapeutic target AUC_{24h}/MIC (400-600) between [48-72] h after start of treatment, when compared to the use of standard-of-care dosing regimens with therapeutic drug monitoring.

Protection of trial subjects:

See attachment

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 December 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 155
Worldwide total number of subjects	155
EEA total number of subjects	155

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)	155
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

see attachment

Pre-assignment

Screening details:

see attachment

Period 1

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

see attachment

Arms

Are arms mutually exclusive?	Yes
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Arm title	Standard-of-care
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Arm description:

See attachment

Arm type	No intervention
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No investigational medicinal product assigned in this arm

Arm title	Intervention
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Arm description:

see attachment

Arm type	Active comparator
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Investigational medicinal product name	Vancomycin
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Solution for solution for infusion
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Routes of administration	Infusion
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Dosage and administration details:

see attachment

Number of subjects in period 1	Standard-of-care	Intervention
Started	78	77
Completed	78	77

Baseline characteristics

End points

End points reporting groups

Reporting group title	Standard-of-care
Reporting group description: See attachment	
Reporting group title	Intervention
Reporting group description: see attachment	

Primary: Primary

End point title	Primary ^[1]
End point description: Proportion of patients reaching target AUC _{24h} /MIC (400-600) between 48h and 72h after start of vancomycin treatment	
End point type	Primary
End point timeframe: During the study	

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: See attachment for more end points

End point values	Standard-of-care	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	78	77		
Units: patients	78	77		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

During the study, see attachment

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	0
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Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: See attachment

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