



Clinical trial results:

A multicentric randomised controlled clinical trial to study the impact of bedside model-informed precision dosing of vancomycin in critically ill children.

Summary

EudraCT number	2019-004538-40
Trial protocol	BE
Global end of trial date	14 December 2023

Results information

Result version number	v1 (current)
This version publication date	12 September 2025
First version publication date	12 September 2025
Summary attachment (see zip file)	Final Study Report (2019-004538-40_BENEFICIAL_Final_Study_Report.pdf)

Trial information

Trial identification

Sponsor protocol code	BC-5429
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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, Ghent, Belgium, 9000
Public contact	Hiruz CTU, Ghent University Hospital, +32 93320500, hiruz.ctu@uzgent.be
Scientific contact	Hiruz CTU, Ghent University Hospital, +32 93320500, 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	08 August 2025
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	14 December 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/MIC (400-600) between [24 to 48] 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	28 December 2020
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: 332
Worldwide total number of subjects	332
EEA total number of subjects	332

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)	332
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)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

See attachment

Arms

Arm title	See attachment
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Arm description:

See attachment

Arm type	Active comparator
Investigational medicinal product name	Vancomycin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

See attachment

Number of subjects in period 1	See attachment
Started	332
Completed	332

Baseline characteristics

End points

End points reporting groups

Reporting group title	See attachment
Reporting group description: See attachment	

Primary: primary

End point title	primary ^[1]
End point description: See attachment	
End point type	Primary
End point timeframe: See attachment	

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

End point values	See attachment			
Subject group type	Reporting group			
Number of subjects analysed	332 ^[2]			
Units: units	332			

Notes:

[2] - See attachment

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

See attachment

Adverse event reporting additional description:

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