



Clinical trial results:

Diuretic Treatment in Acute Heart Failure with Volume Overload Guided by Serial Spot Urine Sodium Assessment

Summary

EudraCT number	2021-005426-18
Trial protocol	BE
Global end of trial date	01 July 2024

Results information

Result version number	v1 (current)
This version publication date	19 July 2025
First version publication date	19 July 2025
Summary attachment (see zip file)	Results DECONGEST (EudraCT results reporting DECONGEST.pdf)

Trial information

Trial identification

Sponsor protocol code	DECONGEST_v1.3
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05411991
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University Hospital Brussels
Sponsor organisation address	Laarbeeklaan 101, Jette, Belgium, 1090
Public contact	Centrum voor Hart- en Vaatziekten, UZ Brussel, +32 24774111,
Scientific contact	Centrum voor Hart- en Vaatziekten, UZ Brussel, +32 24774111,

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	17 September 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 July 2024
Global end of trial reached?	Yes
Global end of trial date	01 July 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate whether a diuretic regimen with low-threshold use of combination diuretic therapy, based on serial assessment of sodium concentration on spot urine samples after diuretic administration, improves decongestion in AHF.

Protection of trial subjects:

Anticipated adverse events, potentially related to the study intervention, include arterial hypotension, acute kidney injury (AKI) and electrolyte disorders. Arterial blood pressure is evaluated throughout the study protocol with continuous invasive measurements or frequent non invasive assessment by cuff manometry. Serum creatinine, eGFR, and serum electro-lyte levels are followed on a daily base during the administration of intravenous diuretics according to the study protocol and afterwards at the discretion of the treating physician. Prespecified safety protocols were in place for such events.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 December 2022
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: 107
Worldwide total number of subjects	107
EEA total number of subjects	107

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)	11
From 65 to 84 years	62

85 years and over	34
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Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	107
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Number of subjects completed	104
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Pre-assignment subject non-completion reasons

Reason: Number of subjects	Adverse event, non-fatal: 1
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Reason: Number of subjects	Consent withdrawn by subject: 2
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Period 1

Period 1 title	Overall trial (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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Arms

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

Arm type	Standard of care arm
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No investigational medicinal product assigned in this arm

Arm title	Intervention arm
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Arm description: -

Arm type	Experimental
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Investigational medicinal product name	Burinex
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Concentrate for solution for infusion
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Routes of administration	Intravenous bolus use
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Dosage and administration details:

Dose depending on the eGFR: 2 mg for >45 mL/min/1.73m²; 3 mg for 45 30 mL/min/1.73m²; or 4 mg for <30 mL/min/1.73m²

Investigational medicinal product name	Diamox
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Powder for solution for infusion
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Routes of administration	Intravenous bolus use
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Dosage and administration details:

500 mg OD

Number of subjects in period 1^[1]	Standard of care	Intervention arm
Started	52	52
Completed	47	49
Not completed	5	3
Adverse event, serious fatal	4	3
Consent withdrawn by subject	1	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Two subjects withdrew consent before receiving any study intervention. One underwent urgent CABG before receiving any study intervention. Those subjects were excluded from the study.

Baseline characteristics

Reporting groups

Reporting group title	Standard of care
Reporting group description: -	
Reporting group title	Intervention arm
Reporting group description: -	

Reporting group values	Standard of care	Intervention arm	Total
Number of subjects	52	52	104
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			
arithmetic mean	79	81	
standard deviation	± 10	± 10	-
Gender categorical Units: Subjects			
Female	24	21	45
Male	28	31	59
NTproBNP Units: ng/L			
median	4989	4134	
inter-quartile range (Q1-Q3)	2523 to 9014	2423 to 7920	-

End points

End points reporting groups

Reporting group title	Standard of care
Reporting group description: -	
Reporting group title	Intervention arm
Reporting group description: -	
Subject analysis set title	Main analysis
Subject analysis set type	Modified intention-to-treat
Subject analysis set description: All randomized patients that received at least one dose of diuretics according to the study protocol. Patients are analysed according to the treatment group they were allocated to according to the electronic randomization system (irrespective of the actual treatment received).	

Primary: Net treatment benefit for hierarchical composite endpoint

End point title	Net treatment benefit for hierarchical composite endpoint
End point description: Net treatment benefit for the hierarchical composite primary endpoint: 1. 30-day survival 2. Days alive & out of hospital or care facility up to 30 days 3. Relative decrease in NTproBNP from baseline	
End point type	Primary
End point timeframe: 30 days	

End point values	Standard of care	Intervention arm	Main analysis	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	51	52	103	
Units: Percentage of wins				
number (not applicable)	44.16	54.68	103	

Statistical analyses

Statistical analysis title	Generalized pairwise comparison
Comparison groups	Standard of care v Intervention arm
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.357
Method	Generalized pairwise comparison

Adverse events

Adverse events information

Timeframe for reporting adverse events:

30 days

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.1
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Reporting groups

Reporting group title	Standard of care
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Reporting group description: -

Reporting group title	Intervention arm
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Reporting group description: -

Serious adverse events	Standard of care	Intervention arm	
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 51 (35.29%)	9 / 52 (17.31%)	
number of deaths (all causes)	4	3	
number of deaths resulting from adverse events			
Cardiac disorders			
Death			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 51 (7.84%)	3 / 52 (5.77%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 4	0 / 3	
Vasopressive therapy			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 51 (1.96%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	1 / 51 (1.96%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardioversion	Additional description: Urgent		

subjects affected / exposed	1 / 51 (1.96%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
worsening heart failure	Additional description: administration of intravenous diuretics or intensification of oral diuretics leading to hospital admission or urgent evaluation		
subjects affected / exposed	7 / 51 (13.73%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 7	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	3 / 51 (5.88%)	2 / 52 (3.85%)	
occurrences causally related to treatment / all	2 / 3	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	1 / 51 (1.96%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hypocalcaemia			
subjects affected / exposed	0 / 51 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Endocarditis			
subjects affected / exposed	0 / 51 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Standard of care	Intervention arm	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 51 (41.18%)	13 / 52 (25.00%)	
Renal and urinary disorders			

Hypokalaemia			
subjects affected / exposed	21 / 51 (41.18%)	13 / 52 (25.00%)	
occurrences (all)	21	13	

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