EudraCT results reporting DECONGEST study

1. Trial Information

1.1. Sponsor details

EudraCT number	2021-005426-18
Full title of the trial	Diuretic Treatment in Acute Heart Failure With Volume Overload Guided by Serial Spot Urine Sodium Assessment
Responsible researcher (point of contact) - Name - Email address	 - Frederik Verbrugge - frederik.verbrugge@uzbrussel.be

1.2. Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	☐Yes	☒No
- If yes, enter EMA paediatric investigation plan (EMEA PIP code)	Click or tap here to enter text.	
Does article 45 of Regulation (EC) No 1901/2006 apply to this trial?	☐Yes	☒No
Does article 46 of Regulation (EC) No 1901/2006 apply to this trial?	☐Yes	☒No

1.3. Results analysis stage

Date of final analysis (dd/mm/yy)	17/09/24	
Is this the analysis of the primary completion data?	☒Yes	☐No
Primary completion date (dd/mm/yy)	01/07/24	
Global end of trial date reached?	☒Yes	☐No
	Date (dd/mm/yy): 01/07/24	
Was the trial ended prematurely?	☐Yes	☒No

1.4. General information about the trial

Actual start date of recruitment (dd/mm/yy)	12/06/22	
Long term follow-up planned?	☐Yes	☒No
Independent data monitoring committee (IDMC) involvement?	☐Yes	☒No

1.5. Population of trial subjects

Subject number per country	
Country	Actual number of subjects enrolled
a) Belgium	a) 107
Age group breakdown for trial	
Age range	Actual number of subjects enrolled
In utero	0
Preterm newborn infants (gestational age < 37 weeks)	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 65-84 years	62
85 years and over	34

2. Subject Disposition

2.1. Period details

Allocation method (choose one)	☒Randomized – controlled ☐Non-randomized – controlled ☐Not applicable

Blinding used (choose one)	☐Double blind ☐Single blind ☒Not blinded

2.2. Arm Information

Total number of study arms	2

2.2.1. Arm 1

Arm Title	
Arm type (choose one)	☐Experimental ☒Active comparator ☐Placebo ☐No intervention ☒Other
Number of subjects started	52
Number of subjects completed	47
Subject non-completion reason	
Reason	Number of subjects
- Adverse event, non-fatal	0
- Adverse event, serious fatal	4
- Consent withdrawn by subject	1
- Lack of efficacy	0
- Lost to follow-up	0
- Physician decision	0
- Pregnancy	0
- Protocol deviation	0
- Transferred to another arm/group	0

Subject joining reason	
Number of subjects	0

2.2.2. Arm 2

Arm Title	
Arm type (choose one)	☒Experimental ☐Active comparator ☐Placebo ☐No intervention ☐Other
Number of subjects started	52
Number of subjects completed	49
Subject non-completion reason	
Reason	Number of subjects
- Adverse event, non-fatal	0
- Adverse event, serious fatal	3
- Consent withdrawn by subject	0
- Lack of efficacy	0
- Lost to follow-up	0
- Physician decision	0
- Pregnancy	0
- Protocol deviation	0
- Transferred to another arm/group	0
Subject joining reason	
Number of subjects	0

3. Baseline Characteristics

Age and gender are always included as baseline characteristics. Are there other study specific baseline characteristics you would like to report?	☒Yes	☐No
- If yes, which baseline characteristics - Where in your published article can these be found? (e.g. Table 1, column X, row Y)	- NTproBNP - Article not yet published. Will be in Table 1. Results are reported on: https://clinicaltrials.gov/study/NCT05411991#study-record-dates	

4. End point definition

Please describe the primary end points that answer the main objective. Please also provide information on where in your published article these results can be found (e.g. Table X, column Y, row Z).

4.1. End point 1

End point title	
End point type	☒Primary ☐Secondary ☐Other pre-specified ☐Post-hoc
Data can be found here	https://clinicaltrials.gov/study/NCT05411991#study-record-dates
Statistical Analysis	
Statistical analysis title	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	
Comparison groups	Arm 1 vs. Arm 2	
Analysis specification	☒Pre-specified	☐Post-hoc
Analysis type	☐Non-inferiority ☐Equivalence ☒Superiority ☐Other (specify)	
Statistical analysis method	☐ANCOVA ☐ANOVA ☐Chi-squared ☐Chi-squared, corrected ☐Cochran-Mantel-Haenszel ☐Fisher exact ☐Kruskal-wallis ☐Logrank ☐Mantel-Haenszel ☐Mcnemar ☐Mixed models analysis ☐Regression, Cox ☐Regression, Linear ☐Regression, Logistic ☐Sign test ☐t-test, 1-sided ☐t-test, 2-sided ☐Wilcoxon (Mann-Whitney) ☒Other (Generalized pairwise comparison)	

5. Adverse events

5.1. Overview

Timeframe for adverse event reporting (Enter the time point(s) or time period for adverse events assessment)	30 days	
Assessment type	☐Systematic	☒Non-systematic

5.2. Adverse event reporting

5.2.1. Summary

How do you wish to report adverse events?	☐Per arm	☒For all study subjects
Number of subjects affected by serious adverse events	27	
Total number of deaths (all causes)	7	
Total number of deaths resulting from adverse events	0	

5.2.2. Serious adverse event details and values

System organ class	**Number of subjects**	**Event Term (i.e. headache, nausea etc)**	**Occurrences**
Cardiac disorders	12	Need for vasopressor Symptomatic bradycardia Urgent electrical cardioversion of atrial fibrillation Worsening heart failure	1 1 2 8
Endocrine disorders	1	Severe hypocalcemia	1
Infections and infestations	1	Endocarditis	1

Renal and urinary disorders	6	Acute kidney injury leading to hospitalization Hyperkalaemia leading to hospitalization	5 1
Assessment type	☐Systematic	☒Non-systematic	

6. More information

Were there any global substantial amendments to the protocol?	☐Yes	☒No
Were there any global interruptions to the trial?	☐Yes	☒No