



Clinical trial results: Effect of dobutamine on hepatic blood flow during goal-directed hemodynamic therapy.

Summary

EudraCT number	2020-005412-21
Trial protocol	BE
Global end of trial date	25 July 2023

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025
Summary attachment (see zip file)	Results summary (DOBU-Whipple_Summary_EudraCT.pdf)

Trial information

Trial identification

Sponsor protocol code	DOBU-Whipple
-----------------------	--------------

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 93320530, hiruz.ctu@uzgent.be
Scientific contact	Hiruz CTU, Ghent University Hospital, 32 93320530, 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	11 September 2025
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	25 July 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the effect of dobutamine on hepatic blood flow and caval & portal vein pressures during goal-directed hemodynamic therapy in patients undergoing pancreaticoduodenectomy.

Protection of trial subjects:

See attachement

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 September 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: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	30
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

See details in attachment

Pre-assignment

Screening details:

See details in attachment

Period 1

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

Blinding implementation details:

See attachment

Arms

Arm title	Dobutamine
-----------	------------

Arm description:

See details in attachment

Arm type	Active comparator
Investigational medicinal product name	Dobutamine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for infusion
Routes of administration	Infusion

Dosage and administration details:

- 12,5 mg/ml vials of 20 ml (250mg/20ml)
- Dosage 2 – 5 mcg/kg/min (or 0.12 – 0.3 mg/kg/h)
- Maximum dosage in this study: patients will receive a maximum of 5 mcg/kg/min titrated on TBW.
- For informative purposes only: Overall maximum dosage according to the ACC/AHA guidelines is 20 mcg/kg/min (or 1.2 mg/kg/h) titrated on TBW.

Number of subjects in period 1	Dobutamine
Started	30
Completed	30

Baseline characteristics

End points

End points reporting groups

Reporting group title	Dobutamine
Reporting group description:	
See details in attachment	

Primary: Primary

End point title	Primary ^[1]
End point description:	
See details in attachment	
End point type	Primary
End point timeframe:	
Overall 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 details in attachment

End point values	Dobutamine			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: HBF				
number (not applicable)	30			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Overall study

Adverse event reporting additional description:

See attachment

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	0.0
--------------------	-----

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 details in 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