



Clinical trial results:

Hemodynamic profile of terlipressin and octreotide in patients with cirrhosis and portal hypertension. A randomised, single blinded clinical trial. (INFUTER)

Summary

EudraCT number	2019-004328-39
Trial protocol	ES
Global end of trial date	15 July 2023

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	INFUTER
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04353193
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	FRCB-IDIBAPS (Fundació de Recerca Clínic Barcelona – Institut d'Investigacions Biomèdiques August Pi i Sunyer IDIBAPS)
Sponsor organisation address	Rosselló, 149, Barcelona, Spain,
Public contact	FRCB, Fundació Clínic per a la Recerca Biomèdica_FRCB, 34 9322754009838, jcgarcia@clinic.cat
Scientific contact	FRCB, Fundació Clínic per a la Recerca Biomèdica_FRCB, 34 9322754009838, jcgarcia@clinic.cat

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	15 July 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 July 2023
Global end of trial reached?	Yes
Global end of trial date	15 July 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the reduction in HVPG caused by three different regimens at 30 minutes, 1 and 2 hours after its administration. Terlipressin at continuous infusion, terlipressin as a bolus, octreotide as a bolus followed by a continuous infusion.

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki, ICH-GCP guidelines, and applicable EU and national regulations. Informed consent was obtained from all participants prior to any study procedure. Personal data were pseudonymized and handled in compliance with GDPR. Ethics Committee approval was obtained before trial initiation.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 July 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	Spain: 38
Worldwide total number of subjects	38
EEA total number of subjects	38

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)	38
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Screening included informed consent, medical history, physical exam, ECG, and blood tests. Inclusion required cirrhosis, HVPg ≥ 12 mmHg, and stable disease. Exclusion criteria included QT-prolonging drugs, recent bleeding or infection, and hepatic encephalopathy. Non-eligible subjects were replaced.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	TERLINf group

Arm description:

Terlipressin by IV continuous infusion at a rate of 2mg/day (max 4mg/day) during 2 hours

Arm type	Experimental
Investigational medicinal product name	Terlipressin
Investigational medicinal product code	
Other name	Glypressin®
Pharmaceutical forms	Solution for injection
Routes of administration	Infusion

Dosage and administration details:

Terlipressin (Glypressin®) 0.2 mg/ml

Terlipressin continuous infusion. After baseline measurements an infusion at an initial dose corresponding to 2mg/day will be started. If HVPg at min 30 does not exhibit a reduction $>10\%$, the rate of infusion will be increased up to the corresponding dose of 4mg/day dose and the following measurements at 1 and 2 hours will be performed.

Arm title	TERLBOL group
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Arm description:

Terlipressin 1mg IV bolus

Arm type	Active comparator
Investigational medicinal product name	Terlipressin
Investigational medicinal product code	
Other name	Glypressin®
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

Terlipressin (Glypressin®) 0.2 mg/ml

Terlipressin bolus. After baseline measurements, a single intravenous injection of terlipressin 1mg will be administered.

Arm title	OCTR group
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Arm description:

Octreotide 50mcg IV bolus plus continuous infusion at a rate of 50mcg/h during 2 hours

Arm type	Active comparator
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Investigational medicinal product name	Octreotide
Investigational medicinal product code	
Other name	Sandostatin®
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous bolus use , Infusion

Dosage and administration details:

Octreotide (Sandostatin®) 100 mcg/ml.

Octreotide 50mcg IV bolus plus continuous infusion at a rate of 50mcg/h during 2 hours

Number of subjects in period 1	TERLINf group	TERLBOL group	OCTR group
Started	14	12	12
Completed	14	12	12

Baseline characteristics

Reporting groups

Reporting group title	TERLINF group
Reporting group description: Terlipressin by IV continuous infusion at a rate of 2mg/day (max 4mg/day) during 2 hours	
Reporting group title	TERLBOL group
Reporting group description: Terlipressin 1mg IV bolus	
Reporting group title	OCTR group
Reporting group description: Octreotide 50mcg IV bolus plus continuous infusion at a rate of 50mcg/h during 2 hours	

Reporting group values	TERLINF group	TERLBOL group	OCTR group
Number of subjects	14	12	12
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	60.5	58.8	57.9
standard deviation	± 11.9	± 7.5	± 8.2
Gender categorical Units: Subjects			
Female	7	4	1
Male	7	8	11

Reporting group values	Total		
Number of subjects	38		
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years)	0 0 0 0 0 0 0		

From 65-84 years	0		
85 years and over	0		

Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	12		
Male	26		

End points

End points reporting groups

Reporting group title	TERLINF group
Reporting group description: Terlipressin by IV continuous infusion at a rate of 2mg/day (max 4mg/day) during 2 hours	
Reporting group title	TERLBOL group
Reporting group description: Terlipressin 1mg IV bolus	
Reporting group title	OCTR group
Reporting group description: Octreotide 50mcg IV bolus plus continuous infusion at a rate of 50mcg/h during 2 hours	

Primary: Change in hepatic venous pressure gradient (HVPG)

End point title	Change in hepatic venous pressure gradient (HVPG)
End point description: Change in HVPG measured at 30, 60, and 120 minutes following administration of terlipressin (bolus or infusion) or octreotide (bolus + infusion) during hepatic vein catheterization.	
End point type	Primary
End point timeframe: 30 minutes, 1 hour, and 2 hours after administration of the investigational product	

End point values	TERLINF group	TERLBOL group	OCTR group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	14	12	12	
Units: mmHg				
arithmetic mean (standard deviation)				
Basal	18.5 (± 1.4)	18.4 (± 1.5)	20.2 (± 1.5)	
30 minutes	18.6 (± 1.4)	17.5 (± 1.5)	19.2 (± 1.5)	
1 hour	18.2 (± 1.4)	17.7 (± 1.5)	19.2 (± 1.5)	
2 hours	18.3 (± 1.4)	17.5 (± 1.5)	19.2 (± 1.5)	

Statistical analyses

Statistical analysis title	HVPG change over time between treatment groups
Statistical analysis description: Evaluation of hepatic venous pressure gradient (HVPG) changes at baseline, 30 min, 60 min, and 120 min in three treatment groups (TERLINF, TERLBOL, OCTR) using a generalized multilevel mixed-effects model (GLMM) for repeated measures. The model included time × treatment interaction as fixed effects to assess differences in HVPG trajectories.	
Comparison groups	TERLINF group v TERLBOL group v OCTR group

Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	superiority ^[1]
P-value	= 0.85 ^[2]
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	-4.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.85
upper limit	-3.95
Variability estimate	Standard deviation
Dispersion value	1.5

Notes:

[1] - Pre-specified superiority analysis comparing HVPG changes over 2 hours among TERLINf, TERLBOL, and OCTR groups using GLMM.

[2] - No statistically significant difference in HVPG trajectories between treatment groups over time.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

During treatment administration (0–120 min), at 24 hours post-procedure, and at 7-day follow-up clinical visit.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	28.0
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Reporting groups

Reporting group title	TERBOL group
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Reporting group description: -

Reporting group title	OCTR group
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Reporting group description: -

Reporting group title	TERLINF group
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Reporting group description: -

Serious adverse events	TERBOL group	OCTR group	TERLINF group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 14 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	TERBOL group	OCTR group	TERLINF group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 14 (0.00%)
Cardiac disorders			
Desaturation	Additional description: Desaturation during the measurement of cardiopulmonary parameters at the end of the procedure.		
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 September 2020	SM-1. This amendment expands inclusion and exclusion criteria to improve recruitment. Patients with compensated cirrhosis (Child-Pugh A5/A6) are now eligible, in addition to B and C up to 12 points. The bilirubin threshold is increased to 10 mg/dL to allow inclusion of patients with acute alcoholic hepatitis and transient hyperbilirubinemia.
17 February 2023	SM-2

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Small sample size and short observation period may limit generalizability. HVPG changes were not statistically significant across groups.

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/40190717>