Clinical trial results:
Open, randomized clinical trial to evaluate the treatment of First Clostridium difficile infection episodes with bacteriotherapy

Summary

EudraCT number	2017-003147-38
Trial protocol	ES
Global end of trial date	30 January 2025

Results information

Result version number	v1 (current)
This version publication date	07 February 2026
First version publication date	07 February 2026

Trial information

Trial identification

Sponsor protocol code	MICRO.HGUGM.2017-14

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Instituto de Investigación Biosanitaria del Hospital Gregorio Marañón
Sponsor organisation address	c/Doctor Esquerdo 46, Madrid, Spain,
Public contact	Elena Reigadas, Instituto de Investigación Biosanitaria del Hospital Gregorio Marañón. Emilio Bouza Santiago, 34 915868453, helenrei@hotmail.com
Scientific contact	Elena Reigadas, Instituto de Investigación Biosanitaria del Hospital Gregorio Marañón. Emilio Bouza Santiago, 34 915868453, helenrei@hotmail.com

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	30 January 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 January 2025
Global end of trial reached?	Yes
Global end of trial date	30 January 2025
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To compare the recurrence rate to treatment with bacteriotherapy versus conventional treatment with vancomycin

Protection of trial subjects:

Investigators: Ensure ethical conduct, obtain consent, provide care, and report deviations.
Sponsors: Provide insurance/indemnity, oversee quality, and ensure compliant trial conduct.
Key Protections & Principles
Informed Consent
Prioritization
Independent Oversight
Privacy & Confidentiality
Medical Care
Risk/Benefit Assessment
Data Integrity

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 December 2017
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: 48
Worldwide total number of subjects	48
EEA total number of subjects	48

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	24
85 years and over	13

Subject disposition

Recruitment

Recruitment details:

Recruitment of patients attended in HGUGM, Madrid, Spain.

Pre-assignment

Screening details:

Inclusion Criteria:

• Men and Women

• Age >18 years

• Agree and be able to provide informed consent (patient or legal representative).

• Microbiologically confirmed diagnosis of toxigenic Clostridium difficile infection (CDI) with a positive direct toxin test and diarrhea (>3 bowel movements/24 hours) or colonoscopic or histopathologica

Pre-assignment period milestones

Number of subjects started	48
Number of subjects completed	48

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Bacteriotherapy (Fecal Microbiota Transplant)

Arm description:

Bacteriotherapy (Fecal Transplant). Bacteriotherapy is administered according to the following regimen:
• A single administration of 4 capsules. Each capsule contains 0.20 +/- 0.03 g of lyophilized fecal matter, equivalent to 2.1-2.5 x 10^{11} bacterial cells.

Arm type	Experimental
Investigational medicinal product name	Bacteriotherapy (fecal microbiota transplant)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Gastroenteral use

Dosage and administration details:

Bacteriotherapy (Fecal Transplant). Bacteriotherapy is administered according to the following regimen:
• A single administration of 4 capsules. Each capsule contains 0.20 +/- 0.03 g of lyophilized fecal matter, equivalent to 2.1-2.5 x 10^{11} bacterial cells.

Arm title	Vancomycin 125mg/6 h 10 days

Arm description:

Standard treatment Vancomycin 125mg/6 hours for 10 days

Arm type	Active comparator

Investigational medicinal product name	Vancomycin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for oral solution
Routes of administration	Gastroenteral use

Dosage and administration details:

oral vancomycin 125mg/6 hours for 10 days

Number of subjects in period 1	Bacteriotherapy (Fecal Microbiota Transplant)	Vancomycin 125mg/6 h 10 days
Started	24	24
Completed	21	23
Not completed	3	1
Physician decision	2	-
Adverse event, non-fatal	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Bacteriotherapy (Fecal Microbiota Transplant)
Reporting group description:	
Bacteriotherapy (Fecal Transplant). Bacteriotherapy is administered according to the following regimen: • A single administration of 4 capsules. Each capsule contains 0.20 +/- 0.03 g of lyophilized fecal matter, equivalent to 2.1-2.5 x 10^{11} bacterial cells.	
Reporting group title	Vancomycin 125mg/6 h 10 days
Reporting group description:	
Standard treatment Vancomycin 125mg/6 hours for 10 days	

Reporting group values	Bacteriotherapy (Fecal Microbiota Transplant)	Vancomycin 125mg/6 h 10 days	Total
Number of subjects	24	24	48
Age categorical			
years			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	6	11
From 65-84 years	12	12	24
85 years and over	7	6	13
Gender categorical Units: Subjects			
Female	17	20	37
Male	7	4	11

End points

End points reporting groups

Reporting group title	Bacteriotherapy (Fecal Microbiota Transplant)
Reporting group description:	
Bacteriotherapy (Fecal Transplant). Bacteriotherapy is administered according to the following regimen: • A single administration of 4 capsules. Each capsule contains 0.20 +/- 0.03 g of lyophilized fecal matter, equivalent to 2.1-2.5 x 10^{11} bacterial cells.	
Reporting group title	Vancomycin 125mg/6 h 10 days
Reporting group description:	
Standard treatment Vancomycin 125mg/6 hours for 10 days	

Primary: Overall Evolution

End point title	Overall Evolution
End point description:	
The primary variable will be the patient's evolution, classified as positive resolution or poor evolution. Poor evolution includes any of the following: treatment failure; progression of the infection to severe or complicated forms; recurrence; or mortality associated with the infection.	
End point type	Primary
End point timeframe:	
60 days after treatment	

End point values	Bacteriotherapy (Fecal Microbiota Transplant)	Vancomycin 125mg/6 h 10 days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	23		
Units: Total individuals for each categoru				
Poor evolution	5	7		
Complete Resolution	16	16		

Statistical analyses

Statistical analysis title	Comparison Bacteriotherapy vs Standard treatment
Statistical analysis description:	
The comparison of recurrence rates between groups will be performed using the Fisher's exact test, estimating relative risk, absolute risk difference, and 95% confidence intervals.	
Comparison groups	Bacteriotherapy (Fecal Microbiota Transplant) v Vancomycin 125mg/6 h 10 days

Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7403 [1]
Method	Fisher exact
Parameter estimate	Risk ratio (RR)
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.57
Variability estimate	Standard deviation
Dispersion value	0.1841

Notes:

[1] - Bacteriotherapy did not show to be superior to standard treatment for CDI first episodes, the difference was not statistically significant. The sample size was small and did not reach the number of patients sufficient to demonstrate superiority.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

90 days after enrolment

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24

Reporting groups

Reporting group title	Bacteriotherapy (Fecal Microbiota Transplant)

Reporting group description:

Bacteriotherapy (Fecal Transplant). Bacteriotherapy is administered according to the following regimen:
• A single administration of 4 capsules. Each capsule contains 0.20 +/- 0.03 g of lyophilized fecal matter, equivalent to 2.1-2.5 x 10^{11} bacterial cells.

Reporting group title	Vancomycin 125mg/6 h 10 days

Reporting group description:

Standard treatment Vancomycin 125mg/6 hours for 10 days

Serious adverse events	Bacteriotherapy (Fecal Microbiota Transplant)	Vancomycin 125mg/6 h 10 days	
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 24 (45.83%)	10 / 24 (41.67%)	
number of deaths (all causes)	1	2	
number of deaths resulting from adverse events			
Vascular disorders			
Cerebral artery occlusion			
subjects affected / exposed	1 / 24 (4.17%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Transient ischaemic attack			
subjects affected / exposed	1 / 24 (4.17%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			

Cardio-respiratory arrest			
subjects affected / exposed	1 / 24 (4.17%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac failure			
subjects affected / exposed	2 / 24 (8.33%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiogenic shock			
subjects affected / exposed	0 / 24 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Confusional state			
subjects affected / exposed	0 / 24 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Clostridium difficile infection			
subjects affected / exposed	2 / 24 (8.33%)	2 / 24 (8.33%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 24 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Skin ulcer			

subjects affected / exposed	0 / 24 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	1 / 24 (4.17%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal impairment			
subjects affected / exposed	1 / 24 (4.17%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
sepsis	Additional description: sepsis of urinary tract origin		
subjects affected / exposed	1 / 24 (4.17%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 24 (0.00%)	1 / 24 (4.17%)	
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: 1 %

Non-serious adverse events	Bacteriotherapy (Fecal Microbiota Transplant)	Vancomycin 125mg/6 h 10 days	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 24 (16.67%)	2 / 24 (8.33%)	
Vascular disorders			
Syncope			

subjects affected / exposed	1 / 24 (4.17%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Clostridium difficile infection			
subjects affected / exposed	2 / 24 (8.33%)	2 / 24 (8.33%)	
occurrences (all)	2	3	
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 24 (0.00%)	
occurrences (all)	1	0	

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