



Clinical trial results:

ABSORB 2: An explorative study determining the oral antibiotic drug absorption in patients with short bowel syndrome.

Summary

EudraCT number	2019-002587-28
Trial protocol	NL
Global end of trial date	07 January 2022

Results information

Result version number	v1 (current)
This version publication date	24 August 2023
First version publication date	24 August 2023
Summary attachment (see zip file)	Article (Oral antimicrobial agents in patients with short bowel syndrome.pdf)

Trial information

Trial identification

Sponsor protocol code	2019-5165
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Nederlands Trial Register: NL7796

Notes:

Sponsors

Sponsor organisation name	Radboud university medical center
Sponsor organisation address	Geert grooteplein zuid 10, Nijmegen, Netherlands, 6500HB
Public contact	Michelle Gompelman, Radboudumc, 31 243093767, Michelle.Gompelman@radboudumc.nl
Scientific contact	Michelle Gompelman, Radboudumc, 31 243093767, Michelle.Gompelman@radboudumc.nl

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	01 November 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 January 2022
Global end of trial reached?	Yes
Global end of trial date	07 January 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to determine the absorption of orally administered antibiotics in patients with SBS, to guide in clinical decision making when faced with catheter related infections.

Protection of trial subjects:

In general, this study aims to restrict the physical and mental burdens for the subject as much as possible. The physical risks that are introduced by this study to the participants are believed to be minimal. The risk derives from collecting the blood are negligible if performed by well-trained physicians and/or nurses.

Next to this, the antimicrobial agents as prescribed as a single dose, have the potential risk of developing side effects, certain toxicities and allergies or intolerance. These potential risks however, are low since only a single dosage is given and are mostly wellknown because the antibiotics are prescribed frequently.

During the study, there will be sufficient medical health assistance (nurse practitioners, attending physician or principle investigator) present at all times in the hospital and reachable by phone to cope with unexpected events.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 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	Netherlands: 18
Worldwide total number of subjects	18
EEA total number of subjects	18

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)	9
From 65 to 84 years	9
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants will be included at the outpatient clinic of the Radboudumc Gastroenterology and Hepatology department. Patients with an indication for HPN training or other intervention that requires elective admission without presence of exclusion criteria for the study will be asked by their treating physician to participate in the study.

Pre-assignment

Screening details:

Due to the explorative nature of the study, no blinding will be performed. After checking the inclusion- and exclusion criteria by the physician/principal investigator and informed consent is given, 8 patients are assigned to the CC-group and the other 8 patients to the FF-group.

Period 1

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

Arms

Arm title	Everyone
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	fluconazole
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for oral suspension, Capsule
Routes of administration	Enteral use , Infusion

Dosage and administration details:

Flucanazole 400mg IV and oral dose (suspension) is an antifungal agent belonging to the triazole class.

Investigational medicinal product name	Ciprofloxacin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Suspension for oral suspension
Routes of administration	Enteral use , Infusion

Dosage and administration details:

Ciprofloxacin 750mg oral dose (suspension) and 400mg IV dose, is a fluoroquinolone antibiotic.

Investigational medicinal product name	Clindamycin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Suspension for oral suspension
Routes of administration	Enteral use , Infusion

Dosage and administration details:

Clindamycin 600mg IV and oral dose (suspension) belongs to the lincosamide class

Investigational medicinal product name	Flucloxacillin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Suspension for oral suspension
Routes of administration	Enteral use , Infusion

Dosage and administration details:

Flucloxacillin 1000mg IV and oral dose (tablet/suspension) is a beta-lactam antibiotic.

Number of subjects in period 1	Everyone
Started	18
Completed	18

Baseline characteristics

Reporting groups

Reporting group title	Full study
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Reporting group description: -

Reporting group values	Full study	Total	
Number of subjects	18	18	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	9	9	
From 65-84 years	9	9	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	59		
standard deviation	± 17	-	
Gender categorical			
Units: Subjects			
Female	10	10	
Male	8	8	

Subject analysis sets

Subject analysis set title	Full analysis
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Subject analysis set type	Full analysis
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Subject analysis set description:

full analysis

Reporting group values	Full analysis		
Number of subjects	18		
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)	9		

From 65-84 years	9		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean	59		
standard deviation	± 17		
Gender categorical			
Units: Subjects			
Female	10		
Male	8		

End points

End points reporting groups

Reporting group title	Everyone
Reporting group description: -	
Subject analysis set title	Full analysis
Subject analysis set type	Full analysis
Subject analysis set description:	
full analysis	

Primary: Oral bioavailability

End point title	Oral bioavailability ^[1]
End point description:	

End point type	Primary
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End point timeframe:

Oral bioavailability of ciprofloxacin, clindamycin, flucloxacillin and fluconazole in patients with SBS.

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: Please see article voor statistical analysis

End point values	Everyone	Full analysis		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	18	18		
Units: %				
number (not applicable)	18	18		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

We reported the adverse events after adverse event on toetsing online.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	1
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Reporting groups

Reporting group title	Everyone
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Reporting group description: -

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: No non-serious adverse events

Serious adverse events	Everyone		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 18 (5.56%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Inguinal pain	Additional description: During the study, one female participant developed severe inguinal pain. The diagnosis was a psoas hematoma following a fall a few days before while having a dysregulated (high) anticoagulant (warfarin) level.		
subjects affected / exposed ^[2]	1 / 1 (100.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Notes:

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: This is correct

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

Non-serious adverse events	Everyone		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 18 (0.00%)		

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