



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 |
|-----------------------|-----------|

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 |
|-----------------------|------------|

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 |
|----------------------------|---------------|

| | |
|---------------------------|---------------|
| Subject analysis set type | Full analysis |
|---------------------------|---------------|

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 |
|----------------|---------|

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 |
|-----------------|------------|

Dictionary used

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

| | |
|--------------------|---|
| Dictionary version | 1 |
|--------------------|---|

Reporting groups

| | |
|-----------------------|----------|
| Reporting group title | Everyone |
|-----------------------|----------|

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