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

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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.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Gastrointestinal motility and defaecation conditions |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON48315

**Source**
ToetsingOnline

**Brief title**
ABSORB2

### Condition

- Gastrointestinal motility and defaecation conditions
- Bacterial infectious disorders

**Synonym**
short bowel syndrome, surgical bowel resection

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** antibiotic absorption, short bowel syndrome

## Outcome measures

### Primary outcome

Main study parameters/endpoints: The primary endpoint of the study is the

enteral absorption of flucloxacillin, clindamycin, ciprofloxacin and

fluconazole, defined as the relative oral bioavailability (in percentage) of

the administered dose in blood plasma concentration.

### Secondary outcome

Secondary study parameters are:

* Comparison results of IV and PO dose and with results of the *normal

population*

* Cmax and time to reach Cmax (Tmax) derived from a plasma concentration curve,

consisting of at least 4 measurements in blood plasma (T=0,1,2,4,8).

* Blood biochemical analysis

* Demographic information, medical history, concomitant medication

* Complications or adverse events

# Study description

### Background summary

Administering oral antibiotics In patients with short bowel syndrome can be

problematic since the changes in anatomy of the gastrointestinal tract with a diminished absorptive capacity result in alterations in drug disposition. Besides this, the bioavailability of oral drugs is primarily affected by reduced bowel length. For this reason, the American Gastroenterological Association (AGA, 2003) advises prolonged intravenous therapy in patients with SBS. Other concomitant factors influence drug absorption and metabolism in the case of short bowel as well, such as mucosal integrity, intestinal motility, site of drug absorption, type of formulation, presence of co-morbidities, pH and parenteral nutrition-associated metabolic changes (Ward et al. 2010). However, successful treatment with orally administered antimicrobial agents has been reported in selected, mostly pediatric, cases with SBS (Dressman et al. 1993, Iacono et al. 1993, Joe et al. 1994, Parsons et al. 1977, Thielman et al. 1998). Unfortunately, more recent, let alone well-designed interventional studies researching biologic availability and other pharmacokinetic parameters of antimicrobial agents in HPN patients with SBS are completely lacking

## Study objective

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.

## Study design

Explorative single-centre study (research with a medicinal product)

## Intervention

Intervention : A single dose of two registered antibiotics will be administered. At four time points blood will be drawn. The CC-Group (n=8) will receive a single oral (day 1) and IV (day 3) dose of Clindamycin 600mg and Ciprofloxacin 750 (400mg IV) mg. Group FF (n=8) will receive a single oral (day 1) and IV (day 3) dose of Flucloxacillin 1000mg and Fluconazol 400mg .

## Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Possible risks associated with participation are adverse reactions to the administration of antibiotics, however as all antibiotics are given as a single dose, and patients will be questioned about allergic reactions to antibiotics, we deem this risk to be low. Since we mostly will obtain blood from the patient*s own central venous access, occurrence of side effects or adverse events related to vena punctures will be rare. Blood will be obtained (withdrawal of approximately 10 ml in total) at four time intervals, mostly during a routine scheduled daytime care visit or hospital admission (for HPN training). There are no extra site visits necessary.

HPN patients, and likely other patient groups with reduced bowel length, will benefit from an evidence-based individualized antibiotic treatment guideline in case of an infection. Ultimately, this will lead to a reduced hospitalization rate with reduced length of stay and subsequently, a reduction in health care related costs. Also this study will provide guidance for further policy development and implementation of antibiotic drug administration protocols specific for patients with reduced bowel length.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

- Patients with current use of long-term home parenteral nutrition (at least 3 consecutive months) and clinically stable
- Diagnosed with SBS (total small bowel length 200cm or less after Treitz

ligamentum)
- Age 18 years of older
- Signed Informed Consent
- Patient is fully able to understand the nature of the proposed intervention.

### Exclusion criteria

- Active vomiting, worsening or new diarrhea
- Contra-indications (for example allergies or interfering co-medication) for any of the study treatments
- Impaired renal function (creatinin clearance <30ml/min/1,73m2)
- Pregnancy
- Morbid obesity (BMI >35)
- Any current or prior medical condition that may interfere with the conduct of the study or the evaluation of its results in the opinion of the investigator

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 23-07-2020 |
| Enrollment: | 16 |
| Type: | Actual |

### Medical products/devices used

| | |
|---|---|
| Product type: | Medicine |

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|---|---|
| Brand name: | ciprofloxacin |
| Generic name: | ciprofloxacin |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | clindamycin |
| Generic name: | clindamycin |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | flucloxacillin |
| Generic name: | flucloxacillin |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | fluconazole |
| Generic name: | fluconazole |
| Registration: | Yes - NL intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 22-08-2019 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 25-02-2020 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2019-002587-28-NL |
| CCMO | NL70700.091.19 |
| Other | NL7796 |

# Study results

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|---|---|
| Date completed: | 07-01-2022 |
| Actual enrolment: | 18 |