

How well is the blood thinner apixaban absorbed in people with short bowel syndrome?

Submission date 02/07/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/07/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/07/2025	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Patients with short bowel syndrome (SBS) may not absorb medications normally due to reduced intestinal surface area. This study aims to find out whether a common blood thinner called apixaban is absorbed well in patients with SBS.

Who can participate?

Patients aged 18 years and over with SBS who are stable and already receiving apixaban as part of their routine care.

What does the study involve?

Participants attend one visit during which blood samples are taken at specific times after their morning dose of apixaban. No other procedures or treatments are involved.

What are the possible benefits and risks of participating?

There is no direct benefit to participants, but the results may help guide future dosing recommendations. Risks are minimal and limited to blood sampling.

Where is the study run from?

The study is being conducted at the 4th Department of Internal Medicine, General University Hospital in Prague, Czech Republic.

When is the study starting and how long is it expected to run for?

June 2023 to April 2025

Who is funding the study?

The study is funded by the Ministry of Health of the Czech Republic (project MH CZ-DRO-VFN64165)

Who is the main contact?

Dr Karolína Hronová, karolina.hronova@lf1.cuni.cz

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Karolína Hronová

ORCID ID

<https://orcid.org/0000-0002-1073-0854>

Contact details

Albertov 4

Prague 2

Czech Republic

12800

+420 (0)224968113

karolina.hronova@lf1.cuni.cz

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

MH CZ-DRO-VFN64165

Study information

Scientific Title

Pharmacokinetic profiling of apixaban in patients with short bowel syndrome using Bayesian re-estimation of a published population pharmacokinetic model

Acronym

Api for SBS

Study objectives

To determine whether the pharmacokinetics of apixaban in patients with short bowel syndrome differ from those in patients with intact gastrointestinal tracts, using Bayesian re-estimation of a published population pharmacokinetic model.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 15/06/2023, Ethics Committee of the General University Hospital in Prague (Na Bojisti 1, Prague 2, 12808, Czech Republic; +420(0)224964131; etickakomise@vfn.cz), ref: 700/73

Study design

Single-center non-randomized single-arm observational pharmacokinetic study

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Short bowel syndrome (SBS)

Interventions

Blood samples were obtained to capture the expected peak plasma steady state concentrations (Tmax) of apixaban in outpatients on standard dose as recommended by the treating physician, in accordance with SmPC, following two different sampling schedules: one sample collected 30 minutes prior to single-dose administration and additional samples at 1, 2.5, 3 and 4.5 hours post-dose of the standard apixaban regimen.

Intervention Type

Other

Primary outcome measure

Plasma concentration of apixaban measured by LC-MS/MS at 30 minutes before morning dose, followed by post-dose samples at 1 ± 0.5 , 2.5 ± 0.5 , 3 ± 0.5 , and 4.5 ± 0.5 hours on the day of steady-state sampling

Secondary outcome measures

1. Relationship between apixaban concentrations and clinical covariates (e.g. nutritional status, parenteral nutrition, teduglutide use, bilirubin) assessed on the day of PK sampling
2. Variability in pharmacokinetic parameters calculated using Bayesian re-estimation

Overall study start date

15/06/2023

Completion date

01/04/2025

Eligibility

Key inclusion criteria

1. Adults with SBS type 1–3
2. Clinically stable
3. Receiving apixaban chronically
4. Able to provide informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

13

Total final enrolment

13

Key exclusion criteria

1. Age <18 years
2. Pregnancy or lactation
3. Body mass index (BMI) <18 kg/m²
4. Active IBD
5. Liver failure (Child-Pugh C)
6. <6 weeks after resection
7. Hemodialysis

Date of first enrolment

23/09/2023

Date of final enrolment

30/03/2025

Locations

Countries of recruitment

Czech Republic

Study participating centre

General University Hospital in Prague
4th Department of Internal Medicine
U Nemocnice 2
Prague
Czech Republic
12808

Sponsor information

Organisation

General University Hospital in Prague

Sponsor details

U Nemocnice 2
Prague 2
Czech Republic
12808
+420 (0)224961111
martina.rackova@vfn.cz

Sponsor type

Hospital/treatment centre

Website

<https://www.vfn.cz>

ROR

<https://ror.org/04yg23125>

Funder(s)

Funder type

Government

Funder Name

Ministry of Health of Czech Republic

Results and Publications

Publication and dissemination plan

Planned publication in peer-reviewed journal

Intention to publish date

01/09/2025

Individual participant data (IPD) sharing plan

The dataset generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication