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

Submission date
02/07/2025

Recruitment status
No longer recruiting

Registration date
03/07/2025

Overall study status
Completed

Last Edited
30/09/2025

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Other

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

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

ROR

https://ror.org/04yg23125

Funder(s)

Funder type
Government

Funder Name
Ministry of Health of Czech Republic

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/09/2025	30/09/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes