The treatment of venous thromboembolism with edoxaban in patients with cirrhosis, a pharmacokinetic study.

Published: 09-06-2020
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To assess the safety and effect of edoxaban in Chil-Pugh B cirrhosis.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational invasive

Summary

ID

NL-OMON49068

Source
ToetsingOnline

Brief title
HEPATO study

Condition

- Hepatic and hepatobiliary disorders
- Embolism and thrombosis

Synonym
deep vein thrombosis, Venous thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Tergooi ziekenhuizen
Source(s) of monetary or material Support: Daiichi Pharmaceutical,Daiichi Sankyo

Intervention

Keyword: cirrhosis, edoxaban, farmacokinetics, venous thromboembolism

Outcome measures

Primary outcome

The main study parameter will be a comparison of edoxaban area under the plasma concentration curve (AUC), maximum concentration (Cmax), a thrombin generation test and several other pharmacokinetic and pharmacodynamics parameters between patients with Child-Pugh A and Child-Pugh B cirrhosis and patients without cirrhosis.

Secondary outcome

not applicable

Study description

Background summary

Patients with cirrhosis have an increased risk of developing venous thromboembolism. Direct oral anticoagulants (DOACs) are easier to use than subcutaneous low-molecular-weight heparin or vitamin K antagonists, but not part of the treatment guidelines for venous thromboembolism in patients with Child-Pugh B and C cirrhosis since they were excluded in the large phase III trials. Based on previous retrospective and in-vitro studies on edoxaban in Child-Pugh B cirrhosis, we hypothesise that edoxaban is safe for these patients.

Study objective

To assess the safety and effect of edoxaban in Chil-Pugh B cirrhosis.

Study design

An open-label, prospective cohort study.

Study burden and risks

Patients will be seen in the hospital two times for a series of blood samples. The first time they will come early in the morning and this visit will last approximately five hours. Five blood samples will be taken. The second time wil be planned during routine outpatient follow-up. the first samples will be taken early in the morning (13.5ml) and the second two hours later (13.5ml). Besides possible small hematomas, there is no additional risk in the study procedures.

Contacts

Public
Tergooi ziekenhuizen

van Riebeeckweg 212
Hilvesum 1213XZ
NL
Scientific
Tergooi ziekenhuizen

van Riebeeckweg 212
Hilvesum 1213XZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age >18 years

- Child Pugh A or B cirrhosis as assessed by treating gastroenterologist
- A diagnosis of venous thromboembolism (deep vein thrombosis, pulmonary embolism, portal vein thrombosis) radiologically confirmed with ultrasound, CT-scan, or MRI-scan
- Treatment with edoxaban 60mg 1dd as per the treating gastroenterologist

Exclusion criteria

- Inability to provide informed conesent
- Active malignancy or infection
- Grade III/IV hepatic encephalopathy
- Cognitive disorders or other unfavorable conditions at discretion of treating physician.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-03-2021
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	09-06-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL71675.018.19