The potency of Edoxaban, a blood thinner, in patients with liverdisease.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26370

Source
NTR

Brief title
POET study

Health condition

cirrhosis, anticoagulation

Sponsors and support

Primary sponsor: University Medical Center groningen
Source(s) of monetary or material Support: University Medical Center
Unrestricted grant from Daiichi Sankyo

Intervention

Outcome measures

Primary outcome

the percentual difference in thrombin generation capacity of plasma taken at baseline versus plasma taken at steady state

Secondary outcome

the number of adverse events and the plasma levels of Edoxaban compared to an anti-Xa assay (calibrated for Edoxaban).

Study description

Study design

Day 1, 3 and 7

Intervention

Overview of planned interventions (this will be performed when the subjects are admitted for their screening programme for liver transplantation):

1. Oral administration of Edoxaban 60 mg once a day.

2. Daily Assesment of vital parameters .

3. Thorough physical examination prior to the first gift of Edoxaban and at day 3 and 7.

4. Blood samples (18 ml, with sodium citrate as anticoagulant) will be taken at set time points:

a. 30 minutes before the first gift of Edoxaban

b. 120 minutes after the first gift

c. 120 minutes after the third gift

d. 120 minutes after the seventh gift

Contacts

Public
Hanzeplein 1

S. Bos
Local code BB31, room Y3.177

Groningen 9713 GZ
The Netherlands
telephone nr: +31503610097
Scientific
Hanzeplein 1

S. Bos
Local code BB31, room Y3.177

Groningen 9713 GZ
The Netherlands
telephone nr: +31503610097

Eligibility criteria

Inclusion criteria

• Age > 18 yrs

• Child Pugh A or B cirrhosis

• Informed consent

Exclusion criteria

• Malignancies

• Renal failure requiring intervention with drugs or dialysis

• Weight < 60 kg

• Active infection

• Use of anticoagulant drugs in the past 10 days

• Use of cyclosporine, dronedarone, erythromycin, or ketoconazole

• Documentation of inherited bleeding disorders

• History of hepatic disease (in the controls)

• History of thrombotic disease

• Recent viral infection (less than two weeks prior to participation)

• Recent (variceal) bleeding or known present varices grade 2-3/3

• Pregnancy

• HIV positivity

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2016
Enrollment:	32
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-07-2016
Application type:	First submission

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
NTR-new	NL5800
NTR-old	NTR5955
Other	METC UMCG : METc 2016/226

Study results