An Open-Label Study to Assess the Effects of VMX-C001 in Combination with an Oral FXa DOAC on the Efficacy of Unfractionated Heparin in Healthy Subjects.

Published: 22-12-2022
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This study has been transitioned to CTIS with ID 2024-514339-87-00 check the CTIS register for the current data. Primary:• To assess the effects of VMX-C001 and a DOAC on the anticoagulant effect of unfractionated heparin in healthy subjects....

Ethical review	Approved WMO
Status	Pending
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Interventional

Summary

ID

NL-OMON53545

Source
ToetsingOnline

Brief title
CS0393 VarmX heparin

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
diseases requiring anticoagulation

Research involving
Human

Sponsors and support

Primary sponsor: VarmX B.V.
Source(s) of monetary or material Support: VarmX B.V

Intervention

Keyword: Effects, Efficacy, Open label

Outcome measures

Primary outcome

PD parameters of VMX-C001 and the DOAC on the anticoagulant effect of unfractionated heparin: PT, aPTT, DRVVT, dPT, D-dimer, calibrated automated thrombography (thrombin generation), real time activated clotting time (ACT) recording, and DOAC concentration.

Secondary outcome

• Safety and tolerability parameters include: physical examination, AEs, clinical laboratory values, vital signs, 12-lead electrocardiogram (ECG).

• Immunogenicity: antibodies against VMX-C001 and human coagulation FX in plasma.

Study description

Background summary

VarmX is developing an analogue of FXa, VMX-C001 that is insensitive to the effects or FXa inhibitors, or direct oral anticoagulants (FXaDOACs). It is be used to restore coagulation in patients taking DOACs who are experiencing bleeding or who require reversal ofanticoagulation prior to urgent surgery. This study is designed to simulate the clinical situation of a patient on apixaban, edoxaban or rivaroxaban that is bleeding, requiring heparin after reversal of the apixaban, edoxaban or rivaroxaban with VMX-C001 for ECMO, surgery under cardiopulmonary bypass or other reasons.

Study objective

This study has been transitioned to CTIS with ID 2024-514339-87-00 check the CTIS register for the current data.

Primary:
• To assess the effects of VMX-C001 and a DOAC on the anticoagulant effect of unfractionated heparin in healthy subjects.
Secundary:
• To assess the safety and tolerability of VMX-C001 in a simulated emergency use setting.
• To assess the immunogenicity of VMX-C001.

Study design

Open-label study in healthy subjects

Intervention

VMX-C001 in suspension for intravenous (i.v.) infusion
Apixaban 5 mg tablets or Edoxaban 60 mg tablets or Rivaroxaban 20 mg tablets.
5000 IU/mL heparin sodium for intravenous (i.v.) infusion

Study burden and risks

Since the study is being executed in healthy volunteers, there are no anticipated benefits of the IMP. Please see the IB for further information.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Men and women of any ethnic origin aged between 18 and 49 years of age, inclusive, at the time of Screening.
2. Male subjects must be willing to use appropriate contraception, such as a condom, and to refrain from sperm donation during the study and until 90 days after VMX-C001 administration.
3. Women of child-bearing potential must agree not to attempt to become pregnant and to use a highly effective form of birth control during the study and for 180 days after study drug administration when their sexual partner has not been vasectomized. Highly effective forms of birth control entail the use of combined (estrogen- and progestogen-containing) or progestogen-only hormonal contraception associated with inhibition of ovulation, an intrauterine device (IUD), an intrauterine hormone-releasing system (IUS) or abstinence.
4. Postmenopausal women must have had >=12 months of spontaneous amenorrhea (with documented follicle-stimulating hormone (FSH) >=30 mIU/mL).

Exclusion criteria

1. The subject has been administered VMX-C001 before.
2. The subject has taken piroxicam in the 2 weeks prior to Day 1.
3. The subject has taken any non-aspirin, non-piroxicam NSAID in the week prior to Day 1.
4. The subject requires or has taken during the month prior to Day 1, vitamin K for therapeutic reasons. Vitamin K not taken for therapeutic purposes is acceptable throughout the study, e.g. as part of a multivitamin supplement.
5. The subject is receiving or requires, for any cause, any anticoagulant or antiplatelet therapy including warfarin, clopidogrel or aspirin or any other anticoagulant or antiplatelet agent or has used these therapies in the month

prior to Day 1.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	16-01-2023
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Nap.
Generic name:	Nap.
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Lixiana
Generic name:	edoxaban
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Nap.
Generic name:	Nap.
Product type:	Medicine
Brand name:	Xarelto

Generic name:	rivaroxaban
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	22-12-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-06-2023
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
Other	2021-002215-54
EU-CTR	CTIS2024-514339-87-00
EudraCT	EUCTR2022-003675-41-NL
CCMO	NL83154.056.22