A Phase I, Dose Escalation Study on the Safety, Pharmacokinetics and Pharmacodynamics of Coagulation Factor VIIa (Recombinant) and its Comparability to NovoSevenÂ® in Healthy Male Volunteers Pre-Treated with Fondaparinux

Published: 05-10-2010
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A study to investigate the safety, pharmacokinetics and pharmacodynamics of a new recombinant human factor VIIa in healthy males, compared to Novoseven.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON34613

Source
ToetsingOnline

Brief title
Recombinant human factor VIIa FIH

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
haemophilia

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: GTC Biotherapeutics

Intervention

Keyword: coagulation, factor VIIa, Fondaparinux, NovoSeven

Outcome measures

Primary outcome

Pharmacokinetics of FVIIa (activity and FVIIa antigen)

Pharmacodynamics of FVIIa:

- Thrombin generation assay output (AUC: primary variable);

- activated partial thromboplastin time (aPTT);

- prothrombin time (PT);

- FVIIa activity;

- anti-Xa;

- Prothrombin fragments 1+2 (F1+2);

- D-dimer;

- fibrinogen;

- antithrombin;

- thrombin antithrombin complex (TAT)

Safety:

Physical examinations, ECGs, vital signs, clinical laboratory tests, immunology

tests, and monitoring of adverse events, coagulation parameters.

Secondary outcome

see above

Study description

Background summary

Factor VIIa is a good therapeutic option to treat patients suffering from haemophilia who have developed antibodies against factor VIII or IX.
GTC aims with this new human recombinant factor VIIA to develop a good therapy to treat patients with haemophilia. The safety and efficacy of the new product will be compared to those of Novoseven, a compound that is currently registerd in Europe and the US.

Study objective

A study to investigate the safety, pharmacokinetics and pharmacodynamics of a new recombinant human factor VIIa in healthy males, compared to Novoseven.

Study design

Parallel study, blinded, placebo-controlled. 3 cohorts with increasing doses.

Study burden and risks

The study day is intensive as a consequence of the relatively frequent blood sampling. The insertion of a canule can be painful and result in a bruise.
There is a potential risk for disturbance of coagulation, but the risks for the volunteers are small, and can be treated well if needed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy male volunteers, 19-45 years of age, BMI 19-30 kg/m^2

Exclusion criteria

Bleeding or coagulation disorder, recent trauma, thromboembolic event, history of administration of any rhFVIIa product, positive reaction to rabbit allergens. See protocol for detailed list of exclusion criteria.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2011
Enrollment:	36
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Arixtra
Generic name:	Fondaparinux
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	N/A
Generic name:	human recombinant factor VIIa
Product type:	Medicine
Brand name:	Novoseven
Generic name:	eptacog-&alfa;
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	05-10-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	03-11-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
EudraCT	EUCTR2010-022639-13-NL
CCMO	NL33877.058.10