Efficacy and Safety of NNC 0129-0000-1003 during Surgical Procedures in Patients with Haemophilia A

Published: 14-11-2011
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Primary Objective: * To evaluate the haemostatic effect of N8-GP during surgical procedures in patients with haemophilia A. Secondary Objectives * To evaluate the general safety including immunogenicity of N8-GP when used for prevention and...

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

Summary

ID

NL-OMON44118

Source
ToetsingOnline

Brief title
Pathfinder3

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
blood clotting disorder, Haemophilia A

Research involving
Human

Sponsors and support

Primary sponsor: Novo Nordisk

Source(s) of monetary or material Support: Novo Nordisk B.V. (industrie)

Intervention

Keyword: Haemophilia A, N8-GP, Surgery, Trial

Outcome measures

Primary outcome

Primary Endpoint:

* Haemostatic effect during surgery evaluated by the four-point scale

(excellent, good, moderate or none), assessed by the Investigator/surgeon at

the day of surgery

Secondary outcome

Secondary Endpoints:

* Average consumption of N8-GP during surgery

* Haemostatic effect of N8-GP during the post-operative period Days 1-6 and 7-14

* Average consumption of N8-GP during the post-operative period Days 1-6

* Incidence rate of inhibitors against factor VIII (FVIII) (*0.6 BU/mL)

Study description

Background summary

The rationale for this trial is to investigate efficacy and safety of N8-GP during surgery, and in the Post-operative Period in patients with haemophilia A. A surgery trial is in accordance with the CHMP guideline on Clinical investigation of recombinant and human plasma-derived Factor VIII products (EMA/CHMP/BPWP/144533/2009). The trial will provide information on the bleeding-preventive effect during surgery, the haemostatic effect during and after these procedures and the safety profile of N8-GP in patients with haemophilia A.
One phase 1 trial has been completed with 26 PTPs dosed with N8-GP and had undergone a safety and PK investigation. The phase 1 trial has successfully

been concluded with no safety concerns. No FVIII inhibitors were detected and no treatment related SAEs were reported. The half-life was pro-longed with approximately 1.6-fold compared to the patients previous FVIII product.

Study objective

Primary Objective:
* To evaluate the haemostatic effect of N8-GP during surgical procedures in patients with haemophilia A.

Secondary Objectives
* To evaluate the general safety including immunogenicity of N8-GP when used for prevention and treatment of bleeding throughout the surgical period
* To evaluate the haemostatic effect of N8-GP during the post-operative period
* To evaluate health economic resource use (hospitalisation days) due to surgery

Study design

The trial is a multi-centre, multi-national, open-label, non-randomised, single arm, efficacy and safety trial evaluating N8-GP during surgical procedures in patients with severe (FVIII activity <1%) haemophilia A. In total a minimum of 15 major surgical procedures need to be evaluated in 10-15 patients.
This trial will provide information on the bleeding-preventive efficacy and safety profile of N8-GP when administered before, during and after surgery. Patients enrolled in this trial can be recruited from the pivotal trial (pathfinder2).
This surgery trial consists of a Screening Visit (Visit 1), Day of Surgery (Day 0: Visit 2), Post-operative Period (Days 1-6: Visit 3, Days 7-14: Visit 4) and an EOT Visit (Visit 5).

Intervention

Continued treatment with N8-GP according to treatment regime in pathfinder2 trial in the period prior to the surgery. An initial injection with N8-GP on the day of surgery, and afterwards depending on the patients needs. Besides, surgery related interventions.

Study burden and risks

It's possible that bloodwithdrawals or injections with N8-GP can cause haemorrhages or discomfort. There is also a very small chance of infection on the injection site. The patient could also experience side effects from N8-GP. There is a risk of development of antibodies against N8-GP and/or Factor VIII that could decrease the effectiveness of future treatments with Factor VIII

products.

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

- Ongoing participation in the pathfinder2 (NN7088-3859) trial and having received *5 doses of N8-GP
- Undergoing major surgery

Exclusion criteria

- Known or suspected hypersensitivity to trial product including allergy to hamster protein or

related products
- Previous withdrawal from the pathfinder2 (NN7088-3859) trial after administration of trial product, except interruption due to inclusion in this pathfinder3 trial (NN7088-3860)
- The receipt of any investigational medicinal product (except N8-GP) within 30 days prior to enrolment into the trial.
- FVIII inhibitors * 0.6 BU/mL at screening
- Previous arterial thrombotic events (e.g. myocardial infarction and intracranial thrombosis) or previous deep venous thrombosis or pulmonary embolism (as defined by available medical records)
- Immune modulating or chemotherapeutic medication

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-05-2013
Enrollment:	1
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Not yet known
Generic name:	N8-GP

Ethics review

Approved WMO

Date:	14-11-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-02-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-05-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-06-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-03-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-03-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-04-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-10-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	26-11-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-12-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-06-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-08-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-12-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-02-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-11-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-11-2017

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2011-001144-30-NL
ClinicalTrials.gov	NCT01489111
CCMO	NL38634.078.11