



Clinical trial results:

Pharmacogenetic testing of saliva samples from patients with 5 exposure days to rFVIIa analogue in the adept™ 2 trial.

Summary

EudraCT number	2015-001919-13
Trial protocol	RO
Global end of trial date	15 April 2016

Results information

Result version number	v1 (current)
This version publication date	30 October 2016
First version publication date	30 October 2016

Trial information

Trial identification

Sponsor protocol code	NN1731-4214
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02541942
WHO universal trial number (UTN)	U1111-1169-6103

Notes:

Sponsors

Sponsor organisation name	Novo Nordisk A/S
Sponsor organisation address	Novo Allé, Bagsvaerd, Denmark, 2880
Public contact	Global Clinical Registry (GCR, 1452), Novo Nordisk A/S, clinicaltrials@novonordisk.com
Scientific contact	Global Clinical Registry (GCR, 1452), Novo Nordisk A/S, clinicaltrials@novonordisk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	28 September 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 April 2016
Global end of trial reached?	Yes
Global end of trial date	15 April 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the HLA type and polymorphisms in the FVII gene in patients previously exposed to rFVIIa analogue in the adeptTM2 trial.

Protection of trial subjects:

The trial was approved by local IRBs/IECs before collection of saliva samples. Health authority approval was only requested in Romania.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 April 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 5
Country: Number of subjects enrolled	Greece: 4
Country: Number of subjects enrolled	Serbia: 2
Country: Number of subjects enrolled	Romania: 1
Country: Number of subjects enrolled	Malaysia: 1
Country: Number of subjects enrolled	Thailand: 3
Country: Number of subjects enrolled	Japan: 3
Worldwide total number of subjects	19
EEA total number of subjects	5

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	4

Adults (18-64 years)	15
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The trial was conducted at 16 sites in 7 countries, as follows: Greece: 2 sites; Japan: 3 sites; Malaysia: 1 site, Romania 1 site, Serbia: 2 sites; Thailand: 2 sites; United States: 5 sites.

Pre-assignment

Screening details:

This trial describes pharmacogenetic testing of saliva samples from patients who participated in the completed NN1731-3562 (adeptTM2) phase 3 trial, with 5 or more exposure days to trial product rFVIIa analogue.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Not Applicable

Arms

Arm title	Subjects for analysis
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Arm description:

Patients who participated in the completed NN1731-3562 (adeptTM2) phase 3 trial, with 5 or more exposure days to trial product rFVIIa analogue and/or rFVIIa, were included in this arm.

Arm type	No treatment given
Investigational medicinal product name	No treatment given
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Not mentioned

Dosage and administration details:

No treatment given

Number of subjects in period 1	Subjects for analysis
Started	19
Completed	19

Baseline characteristics

Reporting groups

Reporting group title	Overall Study
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Reporting group description: -

Reporting group values	Overall Study	Total	
Number of subjects	19	19	
Age Categorical			
This table reflects the age of the patients when entering the preceding main trail NN1731-3562.			
Units: Subjects			
Adolescents (12-17 years)	4	4	
Adults (18-64 years)	15	15	
Age Continuous			
This table reflects the age of the patients when entering the preceding main trail NN1731-3562.			
Units: years			
arithmetic mean	25.26		
standard deviation	± 11.69	-	
Gender Categorical			
Units: Subjects			
Female	0	0	
Male	19	19	

End points

End points reporting groups

Reporting group title	Subjects for analysis
Reporting group description: Patients who participated in the completed NN1731-3562 (adeptTM2) phase 3 trial, with 5 or more exposure days to trial product rFVIIa analogue and/or rFVIIa, were included in this arm.	

Primary: To determine the HLA type in patients previously exposed to rFVIIa analogue in the adeptTM2 trial.

End point title	To determine the HLA type in patients previously exposed to rFVIIa analogue in the adeptTM2 trial. ^[1]
End point description: Determination of HLA type in patients who participated in the completed NN1731-3562 (adeptTM2) phase 3 trial, with 5 or more exposure days to trial product rFVIIa analogue and/or rFVIIa.	
End point type	Primary
End point timeframe: Up to 12 months	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There was no statistical analysis planned in the protocol for this trial.

End point values	Subjects for analysis			
Subject group type	Reporting group			
Number of subjects analysed	19 ^[2]			
Units: HLA typing	0			

Notes:

[2] - Results from this trial is communicated in conjunction with the NN1731-3562 trial.

Statistical analyses

No statistical analyses for this end point

Primary: To determine the polymorphisms in the FVII gene in patients previously exposed to rFVIIa analogue in the adeptTM2 trial.

End point title	To determine the polymorphisms in the FVII gene in patients previously exposed to rFVIIa analogue in the adeptTM2 trial. ^[3]
End point description: Determination of polymorphisms in the FVII gene in patients who participated in the completed NN1731-3562 (adeptTM2) phase 3 trial, with 5 or more exposure days to trial product rFVIIa analogue and/or rFVIIa.	
End point type	Primary
End point timeframe: Up to 12 months	

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There was no statistical analysis planned in the protocol for this trial.

End point values	Subjects for analysis			
Subject group type	Reporting group			
Number of subjects analysed	19 ^[4]			
Units: Number	0			

Notes:

[4] - No FVII variation/mutation was found in any of the 19 subjects.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

This is a bio-specimen research study. There is no safety analysis done in this trial.

Adverse event reporting additional description:

Not Applicable.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	Not Applicable (NA).
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Dictionary version	NA
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Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: This is a bio-specimen research study. There is no safety analysis done in this trial.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported