



Clinical trial results:

Efficacy and safety of once-weekly subcutaneous administration of concizumab prophylaxis in patients with haemophilia A and B, with or without inhibitors

Summary

EudraCT number	2019-002641-37
Trial protocol	SE NL
Global end of trial date	26 March 2020

Results information

Result version number	v1 (current)
This version publication date	27 August 2020
First version publication date	27 August 2020
Summary attachment (see zip file)	Cancelled before Active Statement (Cancelled before Active Statement_2019-002641-37.pdf)

Trial information

Trial identification

Sponsor protocol code	NN7415-4580
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	U1111-1235-5858

Notes:

Sponsors

Sponsor organisation name	Novo Nordisk A/S
Sponsor organisation address	Novo Allé, Bagsvaerd, Denmark, 2880
Public contact	Clinical Reporting Anchor and Disclosure (1452), Novo Nordisk A/S, clinicaltrials@novonordisk.com
Scientific contact	Clinical Reporting Anchor and Disclosure (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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	26 March 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	26 March 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the effect of 1.75 mg/kg concizumab administered once-weekly in maintaining adequate control of bleeding in adult and adolescent patients with haemophilia A or B with or without inhibitors

Protection of trial subjects:

Not applicable.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 March 2020
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	Netherlands: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	0
Adults (18-64 years)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or "0 participants", this trial was discontinued with no participants enrolled in the trial.

Pre-assignment

Screening details:

Not Applicable

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	Concizumab
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Arm description:

99999 is "Not applicable" value or "0 participants", this trial was discontinued with no participants enrolled in the trial.

Arm type	Experimental
Investigational medicinal product name	Concizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Not mentioned

Dosage and administration details:

Not Applicable

Number of subjects in period 1	Concizumab
Started	99999
Completed	99999

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	99999	99999	
Age Categorical			
Units: Subjects			
In utero	0	0	
Pre-term newborn - gestational age < 37 wk	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	99999	99999	
From 65-84 years)	0	0	
85 years and over	0	0	
Age Continuous			
Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender Categorical			
Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Concizumab
Reporting group description: 99999 is "Not applicable" value or "0 participants", this trial was discontinued with no participants enrolled in the trial.	

Primary: The number of treated bleeding episodes (spontaneous and traumatic)

End point title	The number of treated bleeding episodes (spontaneous and traumatic) ^[1]
End point description: 99999 is "Not applicable" value or "0 participants", this trial was discontinued with no participants enrolled in the trial.	
End point type	Primary
End point timeframe: Not Applicable	

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: No subjects were enrolled in the trial, hence results are not available

End point values	Concizumab			
Subject group type	Reporting group			
Number of subjects analysed	99999			
Units: Not Applicable	99999			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

99999 is "Not applicable" value or "0 participants", this trial was discontinued with no participants enrolled in the trial.

Adverse event reporting additional description:

Not Applicable

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	0
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Reporting groups

Reporting group title	Concizumab
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Reporting group description:

Concizumab C 100 mg/ml PDS290

Serious adverse events	Concizumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Concizumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		

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: No subjects were enrolled in the trial, hence results are not available

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

99999 is "Not applicable" value or "0 participants", this trial was discontinued with no participants enrolled in the trial.

Notes: