



Clinical trial results:

The effect of subcutaneous injection of Botulinum Toxin A on chronic wound pain in lower extremities, a prospective exploratory study

Summary

EudraCT number	2021-000096-36
Trial protocol	DK
Global end of trial date	22 April 2024

Results information

Result version number	v1 (current)
This version publication date	28 April 2025
First version publication date	28 April 2025

Trial information

Trial identification

Sponsor protocol code	Botox-01
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05426161
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bispebjerg Hospital
Sponsor organisation address	Bispebjerg Bakke 23, Copenhagen , Denmark, 2400
Public contact	Department of Dermatology and Copenhagen Wound Healing Center, Bispebjerg Hospital, Department of Dermatology and Copenhagen Wound Healing Center, Bispebjerg Hospital, lubna.sabah@regionh.dk
Scientific contact	Department of Dermatology and Copenhagen Wound Healing Center, Bispebjerg Hospital, Department of Dermatology and Copenhagen Wound Healing Center, Bispebjerg Hospital, lubna.sabah@regionh.dk

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	19 June 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 April 2024
Global end of trial reached?	Yes
Global end of trial date	22 April 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The aim of the study is to investigate the effect of subcutaneous administration of Botulinum neurotoxin A on chronic wound pain and wound healing in lower extremity ulcer and safety of the treatment.

Protection of trial subjects:

Monitoring and recording all adverse events (pre-defined or not) throughout the duration of the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 2021
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	Denmark: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	3
From 65 to 84 years	6
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients with painful lower extremity wounds for at least 4 weeks with VAS score of 30 mm or more.

Period 1

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

Arms

Arm title	Total
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Botox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

10 units of Botox per cm² wound area were injected around the wound (2-4 injection sites), 1-2 cm from the wound edge subcutaneously

Number of subjects in period 1	Total
Started	10
Completed	10

Baseline characteristics

Reporting groups

Reporting group title	Overall trail
Reporting group description: -	

Reporting group values	Overall trail	Total	
Number of subjects	10	10	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	3	3	
From 65-84 years	6	6	
85 years and over	1	1	
Age continuous			
Units: years			
arithmetic mean	70		
full range (min-max)	46 to 86	-	
Gender categorical			
Units: Subjects			
Female	4	4	
Male	6	6	

Subject analysis sets

Subject analysis set title	Subject analysis set
Subject analysis set type	Full analysis
Subject analysis set description:	
All the patients included in the trail.	

Reporting group values	Subject analysis set		
Number of subjects	10		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	3		

From 65-84 years	6		
85 years and over	1		
Age continuous			
Units: years			
arithmetic mean	70		
full range (min-max)	46 to 86		
Gender categorical			
Units: Subjects			
Female	4		
Male	6		

End points

End points reporting groups

Reporting group title	Total
Reporting group description: -	
Subject analysis set title	Subject analysis set
Subject analysis set type	Full analysis
Subject analysis set description:	
All the patients included in the trial.	

Primary: Primary end point

End point title	Primary end point ^[1]
End point description:	
The proportion of patients whose pain score (mean Visual analogue scale (VAS) score for study day 18-20) decreased by the predefined level of ≥ 20 mm from baseline (before botulinum neurotoxin A injection) to 3 weeks after injection.	
End point type	Primary
End point timeframe:	
3 weeks after botulinum neurotoxin A injection.	

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: Descriptive and statistical analyses were performed using SPSS Statistics. Continuous data were presented by mean and standard deviation (SD) or median and interquartile ranges (IQR), while categorical variables were expressed in proportions and percentages. The Wilcoxon signed-rank test and Spearman's correlation coefficient (r) were used. Statistical significance was defined as $p < 0.05$.

End point values	Total	Subject analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	10	10		
Units: number				
Reduction in VAS ≥ 20 mm	7	7		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the inclusion in the study at the baseline visit to the final visit (3 months after).

Adverse event reporting additional description:

Adverse event was assessed during each visit.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	10
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Reporting groups

Reporting group title	Overall trial
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Reporting group description: -

Serious adverse events	Overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 10 (30.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Surgical and medical procedures			
hospitalization			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 10 (70.00%)		
Skin and subcutaneous tissue disorders			
Eczema, skin infection, fever			
subjects affected / exposed	7 / 10 (70.00%)		
occurrences (all)	1		

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.

Early termination of the trail due to recruitment difficulties leading to small number of subjects analysed (10 only i stead of 13).
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Notes: