EU Clinical Trials Register

Clinical trial results:
Longevity of microwave thermolysis and botulinum toxin A for treatment of axillary hyperhidrosis: a randomized intra-individual trial

Summary

EudraCT number	2021-000877-10
Trial protocol	DK
Global end of trial date	24 April 2023

Results information

Result version number	v1 (current)
This version publication date	24 May 2024
First version publication date	24 May 2024

Trial information

Trial identification

Sponsor protocol code	MWTBTXA

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05057117
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bispebjerg Hospital
Sponsor organisation address	Nielsine Nielsens Vej 17, Copenhagen NV, Denmark, 2400
Public contact	Merete Haedersdal, Bispebjerg Hospital, Department of Dermatology, 0045 24454393, merete.haedersdal@regionh.dk
Scientific contact	Gabriela Lladó Grove, Bispebjerg Hospital, Department of Dermatology, ggro0013@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	24 April 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 April 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The study aim is to assess and compare treatment effect of MWT and BTX-A for axillary hyperhidrosis with focus on longevity. We also aim to assess patient satisfaction, local skin responses and adverse reactions in relation to treatment.

Protection of trial subjects:

Standard treatments and interventions. Telephone follow-up within the first two days, followed by multiple clinical follow-up points. Open contact to the treating clinician in case of questions during the entire trial.

Background therapy:

No other therapies than the interventional treatments

Evidence for comparator:

Comparison of two standard, evidence-based treatments

Actual start date of recruitment	27 September 2021
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy, Scientific research
Long term follow-up duration	1 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	30
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment was conducted in the clinical setting at Dept of Dermatology, Copenhagen University Hospital (Bispebjerg and Gentofte) including patients between 27.09.21 - 19.04.22

Pre-assignment

Screening details:

According to pre-defined inclusion and exclusion criteria

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

N/A

Arms

Are arms mutually exclusive?	No
Arm title	Botulinum Toxin A

Arm description:

Standard treatment with Botulinum Toxin A in one axilla

Arm type	Active comparator
Investigational medicinal product name	Botulinum Toxin A
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

50-100 U (units)

Arm title	Microwave Thermolysis

Arm description:

Standard treatment with microwave thermolysis in the contralateral axilla

Arm type	Medical device

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Botulinum Toxin A	Microwave Thermolysis
Started	30	30
Completed	30	30

Baseline characteristics

Reporting groups

Reporting group title	Overall trial
Reporting group description:	
30 patients at baseline, each receiving treatment with BTX in one axilla and MWT in the contralateral (by randomization)	

Reporting group values	Overall trial	Total	
Number of subjects	30	30	
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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Age at baseline			
Units: years			
median	26		
inter-quartile range (Q1-Q3)	23 to 35	-	
Gender categorical			
Units: Subjects			
Female	20	20	
Male	10	10	
Previous MWT treatment			
prior to study participation			
Units: Subjects			
yes	0	0	
no	30	30	
Previous BTX A treatment			
Prior to study participation			
Units: Subjects			
yes	8	8	
no	22	22	
BMI			
Body Mass Index			
Units: kg/m2			
median	23.1		
inter-quartile range (Q1-Q3)	20.5 to 25.2	-	
BTX no of treatments			
BTX no of treatments previous to study participation			
Units: no. of treatments			

median	4		
inter-quartile range (Q1-Q3)	2.5 to 5	-	

End points

End points reporting groups

Reporting group title	Botulinum Toxin A
Reporting group description:	
Standard treatment with Botulinum Toxin A in one axilla	
Reporting group title	Microwave Thermolysis
Reporting group description:	
Standard treatment with microwave thermolysis in the contralateral axilla	

Primary: Axillary sweat reduction at 6 months FU

End point title	Axillary sweat reduction at 6 months FU
End point description:	
Gravimetric test	
End point type	Primary
End point timeframe:	
baseline compared to 6-months follow-up, comparing deltas for BTX and MWT	

End point values	Botulinum Toxin A	Microwave Thermolysis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: mg/5min				
median (inter-quartile range (Q1-Q3))	32 (20 to 89)	66 (35 to 95)		

Statistical analyses

Statistical analysis title	Wilcoxon signed-rank test
Statistical analysis description:	
nonparametric test of paired data was applied	
Comparison groups	Botulinum Toxin A v Microwave Thermolysis
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.0124 [1]
Method	Wilcoxon (Mann-Whitney)
Notes:	
[1] - In favor of BTX	

Secondary: Axillary sweat reduction at 12 months FU

End point title	Axillary sweat reduction at 12 months FU
End point description:	
Gravimetric test	

End point type	Secondary

End point timeframe:

baseline compared to 12-months follow-up, comparing deltas for BTX and MWT

End point values	Botulinum Toxin A	Microwave Thermolysis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: mg/5min				
median (inter-quartile range (Q1-Q3))	35 (19 to 76)	47 (24 to 80)		

Statistical analyses

Statistical analysis title	Wilcoxon signed-rank test

Statistical analysis description:

nonparametric test of paired data was applied

Comparison groups	Botulinum Toxin A v Microwave Thermolysis
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.9508
Method	Wilcoxon (Mann-Whitney)

Secondary: Axillary sweat HDSS at 6-months

End point title	Axillary sweat HDSS at 6-months

End point description:

Hyperhidrosis Disease Severity Scale 1-4

End point type	Secondary

End point timeframe:

baseline compared to 6-months follow-up, comparing deltas for BTX and MWT

End point values	Botulinum Toxin A	Microwave Thermolysis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: points				
median (inter-quartile range (Q1-Q3))	2 (2 to 2)	2 (2 to 2)		

Statistical analyses

Statistical analysis title	Wilcoxon signed-rank test)
Statistical analysis description:	
nonparametric test of paired data was applied	
Comparison groups	Botulinum Toxin A v Microwave Thermolysis
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	equivalence[2]
P-value	= 0.4142
Method	Wilcoxon (Mann-Whitney)
Notes:	
[2] - Comparing BTX to MWT	

Secondary: Axillary sweat HDSS at 12-months

End point title	Axillary sweat HDSS at 12-months
End point description:	
Hyperhidrosis Disease Severity Scale 1-4	
End point type	Secondary
End point timeframe:	
baseline compared to 12-months follow-up, comparing deltas for BTX and MWT	

End point values	Botulinum Toxin A	Microwave Thermolysis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: points				
median (inter-quartile range (Q1-Q3))	2 (2 to 3)	2 (2 to 3)		

Statistical analyses

Statistical analysis title	Wilcoxon signed-rank test
Statistical analysis description:	
nonparametric test of paired data was applied	
Comparison groups	Botulinum Toxin A v Microwave Thermolysis
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.1025
Method	Wilcoxon (Mann-Whitney)

Secondary: Axillary odor at 6-months FU

End point title	Axillary odor at 6-months FU
End point description:	
Odor Scale 1-10	

End point type	Secondary

End point timeframe:

baseline compared to 6-months follow-up, comparing deltas for BTX and MWT

End point values	Botulinum Toxin A	Microwave Thermolysis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: points				
median (inter-quartile range (Q1-Q3))	3 (2 to 5)	2.5 (2 to 5)		

Statistical analyses

Statistical analysis title	Wilcoxon signed-rank test

Statistical analysis description:

nonparametric test of paired data was applied

Comparison groups	Botulinum Toxin A v Microwave Thermolysis
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.6826
Method	Wilcoxon (Mann-Whitney)

Secondary: Axillary odor at 12-months FU

End point title	Axillary odor at 12-months FU

End point description:

Odor Scale 1-10

End point type	Secondary

End point timeframe:

baseline compared to 12-months follow-up, comparing deltas for BTX and MWT

End point values	Botulinum Toxin A	Microwave Thermolysis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: points				
median (inter-quartile range (Q1-Q3))	4 (2 to 7)	2.5 (2 to 6)		

Statistical analyses

Statistical analysis title	Wilcoxon signed-rank test
Statistical analysis description:	
nonparametric test of paired data was applied	
Comparison groups	Botulinum Toxin A v Microwave Thermolysis
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.0098
Method	Wilcoxon (Mann-Whitney)

Secondary: DLQI at 6-months

End point title	DLQI at 6-months
End point description:	
Dermatology Life Quality Index 0-30	
End point type	Secondary
End point timeframe:	
baseline compared to 6-months follow-up, comparing deltas for BTX and MWT	

End point values	Botulinum Toxin A	Microwave Thermolysis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: points				
median (inter-quartile range (Q1-Q3))	3 (1 to 5)	3 (1 to 6)		

Statistical analyses

Statistical analysis title	Wilcoxon signed-rank test
Statistical analysis description:	
nonparametric test of paired data was applied	
Comparison groups	Botulinum Toxin A v Microwave Thermolysis
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.0857
Method	Wilcoxon (Mann-Whitney)

Secondary: DLQI at 12-months

End point title	DLQI at 12-months
End point description:	
Dermatology Life Quality Index 0-30	

End point type	Secondary

End point timeframe:

baseline compared to 12-months follow-up, comparing deltas for BTX and MWT

End point values	Botulinum Toxin A	Microwave Thermolysis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: points				
median (inter-quartile range (Q1-Q3))	4 (1 to 7)	4 (1 to 7)		

Statistical analyses

Statistical analysis title	Wilcoxon signed-rank test

Statistical analysis description:

nonparametric test of paired data was applied

Comparison groups	Botulinum Toxin A v Microwave Thermolysis
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.3745
Method	Wilcoxon (Mann-Whitney)

Secondary: HidroQoL at 6-months

End point title	HidroQoL at 6-months

End point description:

Hyperhidrosis Quality of Life Index 0-36

End point type	Secondary

End point timeframe:

baseline compared to 6-months follow-up, comparing deltas for BTX and MWT

End point values	Botulinum Toxin A	Microwave Thermolysis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: points				
median (inter-quartile range (Q1-Q3))	8.5 (4 to 15)	8.5 (5 to 15)		

Statistical analyses

Statistical analysis title	Wilcoxon signed-rank test
Statistical analysis description:	
nonparametric test of paired data was applied	
Comparison groups	Botulinum Toxin A v Microwave Thermolysis
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.4374
Method	Wilcoxon (Mann-Whitney)

Secondary: HidroQoL at 12-months

End point title	HidroQoL at 12-months
End point description:	
Hyperhidrosis Quality of Life Index 0-36	
End point type	Secondary
End point timeframe:	
baseline compared to 12-months follow-up, comparing deltas for BTX and MWT	

End point values	Botulinum Toxin A	Microwave Thermolysis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: points				
median (inter-quartile range (Q1-Q3))	11.5 (4 to 19)	11 (3 to 22)		

Statistical analyses

Statistical analysis title	Wilcoxon signed-rank test
Statistical analysis description:	
nonparametric test of paired data was applied	
Comparison groups	Botulinum Toxin A v Microwave Thermolysis
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.1761
Method	Wilcoxon (Mann-Whitney)

Secondary: Procedure-related pain

End point title	Procedure-related pain
End point description:	
VAS 0-10	

End point type	Secondary

End point timeframe:

On-site at baseline treatments, comparing BTX and MWT

End point values	Botulinum Toxin A	Microwave Thermolysis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: points				
median (inter-quartile range (Q1-Q3))	4.5 (3 to 7)	3 (2 to 4)		

Statistical analyses

Statistical analysis title	Wilcoxon signed-rank test

Statistical analysis description:

nonparametric test of paired data was applied

Comparison groups	Botulinum Toxin A v Microwave Thermolysis
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.0001
Method	Wilcoxon (Mann-Whitney)

Secondary: Post-procedural pain

End point title	Post-procedural pain

End point description:

Likert 0-3

End point type	Secondary

End point timeframe:

2 days after baseline treatments

End point values	Botulinum Toxin A	Microwave Thermolysis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: points				
median (inter-quartile range (Q1-Q3))	0 (0 to 0)	1 (1 to 2)		

Statistical analyses

Statistical analysis title	Wilcoxon signed-rank test
Statistical analysis description:	
nonparametric test of paired data was applied	
Comparison groups	Microwave Thermolysis v Botulinum Toxin A
Number of subjects included in analysis	60
Analysis specification	Post-hoc
Analysis type	equivalence
P-value	= 0.3173
Method	Wilcoxon (Mann-Whitney)

Secondary: Patient satisfaction

End point title	Patient satisfaction
End point description:	
Satisfied	
End point type	Secondary
End point timeframe:	
Overall satisfaction at 12-months FU	

End point values	Botulinum Toxin A	Microwave Thermolysis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: points				
number (not applicable)	24	24		

Statistical analyses

No statistical analyses for this end point

Secondary: Hair reduction

End point title	Hair reduction
End point description:	
Likert 0-3	
End point type	Secondary
End point timeframe:	
Baseline compared to 12-month FU, comparing BTX and MWT	

End point values	Botulinum Toxin A	Microwave Thermolysis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: points				
median (inter-quartile range (Q1-Q3))	0 (0 to 0)	2 (2 to 3)		

Statistical analyses

Statistical analysis title	Wilcoxon signed-rank test
Statistical analysis description:	
nonparametric test of paired data was applied	
Comparison groups	Botulinum Toxin A v Microwave Thermolysis
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.0001
Method	Wilcoxon (Mann-Whitney)

Secondary: Patient preference

End point title	Patient preference
End point description:	
Preferred treatment	
End point type	Secondary
End point timeframe:	
at 12-months FU, comparing BTX and MWT	

End point values	Botulinum Toxin A	Microwave Thermolysis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: points				
number (not applicable)	5	23		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

1 year after baseline for each patient

Adverse event reporting additional description:

According to GCP and the Danish Medicines Agency with yearly reports

Assessment type	Systematic

Dictionary used

Dictionary name	None
Dictionary version	0

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

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 non-serious AE/AR above frequency threshold for reporting non-serious adverse events

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/38495540