



Clinical trial results:

A Phase IV, Randomized, Interventional, Study to Assess Subject Treatment Session Perception and Investigator Treatment Experience of Alluzience and Vacuum-Dried Botulinum Neurotoxin Type A for Aesthetic Use

Summary

EudraCT number	2021-004748-62
Trial protocol	DE
Global end of trial date	12 October 2022

Results information

Result version number	v1 (current)
This version publication date	02 February 2024
First version publication date	02 February 2024

Trial information

Trial identification

Sponsor protocol code	05PF2005
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05277337
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Q-Med AB, part of the Galderma Group
Sponsor organisation address	Seminariegatan 21, Uppsala, Sweden, SE-752 28
Public contact	Daniel Seisdedos, Q-Med AB, part of the Galderma Group, Daniel.SeisdedosHedman@galderma.com
Scientific contact	Daniel Seisdedos, Q-Med AB, part of the Galderma Group, Daniel.SeisdedosHedman@galderma.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	12 October 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 October 2022
Global end of trial reached?	Yes
Global end of trial date	12 October 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate time needed to prepare Alluzience and powder BoNT A

Protection of trial subjects:

No invasive assessments were performed and the study product injections were administered according to the SMPC.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 February 2022
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	Germany: 56
Country: Number of subjects enrolled	United Kingdom: 94
Worldwide total number of subjects	150
EEA total number of subjects	56

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)	150
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

153 subjects were screened in Germany and the United Kingdom. 3 subjects were screening failures and 150 subjects were randomised in the study.

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	150
Number of subjects completed	150

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1 (Alluzience)

Arm description:

Alluzience 0.25 mL single dose was administered as an intramuscular injection, through a syringe and needle at baseline visit (Day 0).

Arm type	Experimental
Investigational medicinal product name	Alluzience
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Alluzience is an abobotulinum neurotoxin type A, supplied as a sterile, buffered solution for injection. Each vial contains 125 Speywood units (s.U) in 0.625 mL of solution, i.e., 200 s.U/mL. 10 U/0.05 mL per injection point. In total 50 s.U in 0.25 mL for 5 injection points.

Arm title	Group 2 (Powder BoNT-A: BOTOX/Vistabel)
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Arm description:

Powder BoNT-A 0.5 mL single dose was administered as an intramuscular injection, through a syringe and needle at baseline visit (Day 0).

Arm type	Active comparator
Investigational medicinal product name	Powder BoNT-A: BOTOX/Vistabel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection/infusion
Routes of administration	Intramuscular use

Dosage and administration details:

BOTOX®/Vistabel® is a onabotulinum toxin type A, supplied in a sterile, vacuum-dried form. The vial, containing 50 U, is reconstituted with 1.25 mL of sterile, 0.9% sodium chloride before study treatment. 4 U/0.1 mL per injection point. In total 20 U in 0.5 mL for 5 injection points.

Number of subjects in period 1	Group 1 (Alluzience)	Group 2 (Powder BoNT-A: BOTOX/Vistabel)
Started	99	51
Completed	96	51
Not completed	3	0
Consent withdrawn by subject	1	-
Lost to follow-up	2	-

Baseline characteristics

Reporting groups

Reporting group title	Group 1 (Alluzience)
Reporting group description: Alluzience 0.25 mL single dose was administered as an intramuscular injection, through a syringe and needle at baseline visit (Day 0).	
Reporting group title	Group 2 (Powder BoNT-A: BOTOX/Vistabel)
Reporting group description: Powder BoNT-A 0.5 mL single dose was administered as an intramuscular injection, through a syringe and needle at baseline visit (Day 0).	

Reporting group values	Group 1 (Alluzience)	Group 2 (Powder BoNT-A: BOTOX/Vistabel)	Total
Number of subjects	99	51	150
Age categorical Units: Subjects			
Adults (18-64 years)	99	51	150
Age continuous			
Age, Continuous			
Units: years			
arithmetic mean	45.9	44.6	
standard deviation	± 10.27	± 10.91	-
Gender categorical Units: Subjects			
Female	99	51	150
Male	0	0	0
Race/Ethnicity Units: Subjects			
White	94	49	143
Black or African American	1	1	2
Asian	1	1	2
Other Asian	2	0	2
Other	1	0	1

Subject analysis sets

Subject analysis set title	Full Analysis Set
Subject analysis set type	Full analysis
Subject analysis set description: Full Analysis Set (FAS) Efficacy Population: The FAS was to include all randomized and treated subjects. FAS will be used for all efficacy evaluations.	
Subject analysis set title	Per-protocol
Subject analysis set type	Per protocol
Subject analysis set description: Per-protocol (PP) Efficacy Population: The Per Protocol (PP) population was a subset of the subjects in the FAS population who completed the Month 1 visit and had no protocol deviations considered to have a substantial impact on the primary efficacy outcome. The primary efficacy endpoint was to be evaluated using the PP population if the PP population consisted of less than 95% of the FAS population.	
Subject analysis set title	Safety Population

Subject analysis set type	Safety analysis
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Subject analysis set description:

Safety Population: The safety population was to include all subjects who were administered study product (i.e., Alluzience or powder BoNT-A). Safety analysis were to be performed based on the Safety population.

Reporting group values	Full Analysis Set	Per-protocol	Safety Population
Number of subjects	150	150	150
Age categorical			
Units: Subjects			
Adults (18-64 years)	150	150	150
Age continuous			
Age, Continuous			
Units: years			
arithmetic mean	45.4	45.4	45.4
standard deviation	± 10.47	± 10.47	± 10.47
Gender categorical			
Units: Subjects			
Female	150	150	150
Male	0	0	0
Race/Ethnicity			
Units: Subjects			
White	143	143	143
Black or African American	2	2	2
Asian	2	2	2
Other Asian	2	2	2
Other	1	1	1

End points

End points reporting groups

Reporting group title	Group 1 (Alluzience)
Reporting group description: Alluzience 0.25 mL single dose was administered as an intramuscular injection, through a syringe and needle at baseline visit (Day 0).	
Reporting group title	Group 2 (Powder BoNT-A: BOTOX/Vistabel)
Reporting group description: Powder BoNT-A 0.5 mL single dose was administered as an intramuscular injection, through a syringe and needle at baseline visit (Day 0).	
Subject analysis set title	Full Analysis Set
Subject analysis set type	Full analysis
Subject analysis set description: Full Analysis Set (FAS) Efficacy Population: The FAS was to include all randomized and treated subjects. FAS will be used for all efficacy evaluations.	
Subject analysis set title	Per-protocol
Subject analysis set type	Per protocol
Subject analysis set description: Per-protocol (PP) Efficacy Population: The Per Protocol (PP) population was a subset of the subjects in the FAS population who completed the Month 1 visit and had no protocol deviations considered to have a substantial impact on the primary efficacy outcome. The primary efficacy endpoint was to be evaluated using the PP population if the PP population consisted of less than 95% of the FAS population.	
Subject analysis set title	Safety Population
Subject analysis set type	Safety analysis
Subject analysis set description: Safety Population: The safety population was to include all subjects who were administered study product (i.e., Alluzience or powder BoNT-A). Safety analysis were to be performed based on the Safety population.	

Primary: Time Needed to Prepare Alluzience and Powder BoNT A

End point title	Time Needed to Prepare Alluzience and Powder BoNT A
End point description: Time to prepare Alluzience and powder BoNT-A for administration was collected for all subjects.	
End point type	Primary
End point timeframe: Baseline (Day 0)	

End point values	Group 1 (Alluzience)	Group 2 (Powder BoNT-A: BOTOX/Vistabel)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	99 ^[1]	51 ^[2]		
Units: Minutes				
arithmetic mean (standard deviation)	0.55 (± 0.414)	1.57 (± 0.831)		

Notes:

[1] - FAS

[2] - FAS

Statistical analyses

Statistical analysis title	Equality of Variance Test T-Test
Statistical analysis description: The average preparation time will be compared between the two groups using a t-test. Equality of variances between groups will be tested and the Satterthwaite approximation will be used if the variances are unequal. If it is not the case, Pooled variances will be used. The difference of preparation time, corresponding 95% confidence intervals based on the test used and p-value will be presented.	
Comparison groups	Group 1 (Alluzience) v Group 2 (Powder BoNT-A: BOTOX/Vistabel)
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.26
upper limit	-0.77
Variability estimate	Standard deviation
Dispersion value	0

Secondary: Percentage of Participants Injected With Alluzience for Whom the Investigator did NOT Faced Technical Issue/Problems When Using a Ready-to-use Product as Compared to a Product to be Reconstituted

End point title	Percentage of Participants Injected With Alluzience for Whom the Investigator did NOT Faced Technical Issue/Problems When Using a Ready-to-use Product as Compared to a Product to be Reconstituted ^[3]
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End point description:

Percentage of participants injected with Alluzience for whom investigator faced technical issue/problems when using a ready-to-use product as compared to a product to be reconstituted, assessed using answers within each answer option (strongly agree, agree, neither agree nor disagree, disagree and strongly disagree) was reported.

End point type	Secondary
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End point timeframe:

Baseline (Day 0)

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only descriptive statistics were used for this end point.

End point values	Group 1 (Alluzience)			
Subject group type	Reporting group			
Number of subjects analysed	99 ^[4]			
Units: %				
number (not applicable)				
Strongly Agree	91.9			
Agree	8.1			

Notes:

[4] - FAS - Arm 1

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Injected With Powder Bont-A for Whom Investigator Experienced Issues While Reconstitution

End point title	Percentage of Participants Injected With Powder Bont-A for Whom Investigator Experienced Issues While Reconstitution ^[5]
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End point description:

Percentage of participants injected with Powder Bont-A for whom investigator experienced issues while reconstitution was assessed using a questionnaire (Yes/No). Percentage of participants with answer "Yes" was reported.

End point type	Secondary
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End point timeframe:

Baseline (Day 0)

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive statistics were used for this end point.

End point values	Group 2 (Powder BoNT-A: BOTOX/Vistabel)			
Subject group type	Reporting group			
Number of subjects analysed	51 ^[6]			
Units: %				
number (not applicable)				
Yes	2			
No	98			

Notes:

[6] - FAS - Arm 2

Statistical analyses

No statistical analyses for this end point

Secondary: Investigator Treatment Session Questionnaire

End point title	Investigator Treatment Session Questionnaire ^[7]
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End point description:

The Investigator Treatment Session Questionnaire was completed by the Treating Investigator after the subject has been treated at Visit 2 (baseline). The questionnaire was only completed for Alluzience treated subjects.

End point type	Secondary
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End point timeframe:

Post-treatment at baseline (VIsit 2)

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive statistics were used for this end point.

End point values	Group 1 (Alluzience)	Full Analysis Set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	99	150		
Units: %	99	99		

Attachments (see zip file)	Investigator Treatment Session Questionnaire/1 Table 14.2.6
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Statistical analyses

No statistical analyses for this end point

Secondary: Usability Questionnaire

End point title	Usability Questionnaire
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End point description:

The Usability Questionnaire was completed by the Treating Investigators who have been both reconstituting and administering study product. The questionnaire was completed once per Treating Investigator at the sites and was answered for each treatment separately, i.e. once for Alluzience and once for powder BoNT-A. All subjects planned to be enrolled at the site had completed Visit 2 (baseline) when the questionnaire was completed.

End point type	Secondary
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End point timeframe:

After all subjects had been treated at the Investigator's study site.

End point values	Group 1 (Alluzience)	Group 2 (Powder BoNT-A: BOTOX/Vistabel)	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	99	51	150 ^[8]	
Units: %	0	0	0	

Notes:

[8] - Only one questionnaire collected per Treating Investigator (n=21)

Attachments (see zip file)	Usability Questionnaire/2 Table 14.2.8 Usability Questionnaire.
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Statistical analyses

No statistical analyses for this end point

Secondary: Subject Treatment Session Questionnaire

End point title	Subject Treatment Session Questionnaire
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End point description:

The Subject Treatment Session Questionnaire was completed by all treated subjects after treatment at Visit 2 (baseline). The questionnaire is divided into two treatment-specific sections, one for Alluzience and one for powder BoNT-A.

End point type	Secondary
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End point timeframe:

Post-treatment at baseline (Visit 2).

End point values	Group 1 (Alluzience)	Group 2 (Powder BoNT-A: BOTOX/Vistabel)	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	99	51	150	
Units: %	0	0	0	

Attachments (see zip file)	Subject Treatment Session Questionnaire/3 Table 14.2.5.1
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Statistical analyses

No statistical analyses for this end point

Secondary: Global Aesthetic Improvement Scale

End point title	Global Aesthetic Improvement Scale ^[9]
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End point description:

At all post-treatment visits for the Alluzience treated subjects (Group 1), subjects and the Investigator rated the global aesthetic improvement of their GL at rest and at maximum frown, relative to their pre-treatment appearance by using the Global Aesthetic Improvement Scale (GAIS).

End point type	Secondary
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End point timeframe:

All post-treatment visits after baseline.

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only descriptive statistics were used for this end point.

End point values	Group 1 (Alluzience)	Full Analysis Set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	99	99		
Units: %	0	0		

Attachments (see zip file)	Global Aesthetic Improvement Scale /4 Table 14.2.7.1 Global
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Statistical analyses

No statistical analyses for this end point

Secondary: Subject Satisfaction Questionnaire

End point title	Subject Satisfaction Questionnaire
End point description: The Subject Treatment Session Questionnaire was completed by all treated subjects after treatment at Visit 2 (baseline). The questionnaire is divided into two treatment-specific sections, one for Alluzience and one for powder BoNT-A.	
End point type	Secondary
End point timeframe: Post-treatment at baseline (Visit 2).	

End point values	Group 1 (Alluzience)	Group 2 (Powder BoNT-A: BOTOX/Vistabel)	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	99	51	150	
Units: %	0	0	0	

Attachments (see zip file)	Subject Satisfaction Questionnaire/5 Table 14.2.4.1 Subject
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Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from treatment until the end of the participant's participation (upto 6 months). The safety population was to include all participants who were administered study product.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.1
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Reporting groups

Reporting group title	Group 1 (Alluzience)
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Reporting group description: -

Reporting group title	Group 2 (Powder BoNT-A: BOTOX/Vistabel)
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Reporting group description: -

Serious adverse events	Group 1 (Alluzience)	Group 2 (Powder BoNT-A: BOTOX/Vistabel)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99 (0.00%)	0 / 51 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Group 1 (Alluzience)	Group 2 (Powder BoNT-A: BOTOX/Vistabel)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 99 (26.26%)	1 / 51 (1.96%)	
Investigations			
SARS-CoV-2 test positive			
subjects affected / exposed	1 / 99 (1.01%)	0 / 51 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 99 (4.04%)	0 / 51 (0.00%)	
occurrences (all)	4	0	
Tension headache			

subjects affected / exposed occurrences (all)	2 / 99 (2.02%) 2	0 / 51 (0.00%) 0	
Hypoaesthesia subjects affected / exposed occurrences (all)	1 / 99 (1.01%) 1	0 / 51 (0.00%) 0	
General disorders and administration site conditions			
Injection site pain subjects affected / exposed occurrences (all)	11 / 99 (11.11%) 11	0 / 51 (0.00%) 0	
Injection site haematoma subjects affected / exposed occurrences (all)	1 / 99 (1.01%) 1	0 / 51 (0.00%) 0	
Injection site pruritus subjects affected / exposed occurrences (all)	1 / 99 (1.01%) 1	0 / 51 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	1 / 99 (1.01%) 1	0 / 51 (0.00%) 0	
Infections and infestations			
COVID-19 subjects affected / exposed occurrences (all)	5 / 99 (5.05%) 5	1 / 51 (1.96%) 1	
Nasopharyngitis subjects affected / exposed occurrences (all)	2 / 99 (2.02%) 2	0 / 51 (0.00%) 0	

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