ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 06/17/2015

ClinicalTrials.gov ID: NCT00618618

Study Identification

Unique Protocol ID:	ATX-101-07-07
Brief Title:	Phase 2 Study of Deoxycholic Acid Injection (ATX-101) for the Reduction of Submental Fat
Official Title:	Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study of the Safety and Efficacy of ATX-101 (Sodium Deoxycholate for Injection) Given by Three Dosing Paradigms for the Reduction of Localized Subcutaneous Fat in the Submental Area
Secondary IDs:	2007-006303-21 [EudraCT Number]

Study Status

Record Verification:	June 2015
Overall Status:	Completed
Study Start:	April 2008
Primary Completion:	December 2008 [Actual]
Study Completion:	December 2008 [Actual]

Sponsor/Collaborators

Sponsor:	Kythera Biopharmaceuticals
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes

Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: 79,726 Serial Number: Has Expanded Access? No
Review Board:	Approval Status: Approved Approval Number: 01/15/08 Board Name: Bellberry Human Research Ethics Committee Board Affiliation: Independent Phone: Email: www.bellberry@bigpond.com
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Australia: National Health and Medical Research Council United Kingdom: Medicines and Healthcare Products Regulatory Agency Canada: Health Canada United States: Food and Drug Administration

Study Description

Brief Summary:	Phase 2 trial to evaluate the safety and potential efficacy of one concentration of deoxycholic acid injection, given in three dosing paradigms, compared to placebo for the reduction of submental fat (fat beneath the chin).
Detailed Description:	

Conditions

Conditions:	Moderate or Severe Submental Fullness
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2

Intervention Model:	Parallel Assignment
Number of Arms:	6
Masking:	Double Blind (Subject, Investigator)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	73 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Deoxycholic Acid Injection 0.2 mL/0.7 cm Participants received deoxycholic acid administered in 0.2 mL injections, 0.7 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.	Drug: Deoxycholic Acid Injection Formulated as an injectable solution containing deoxycholic acid at a concentration of 10 mg/mL. Other Names: • ATX-101
Placebo Comparator: Placebo 0.2 mL/0.7 cm Participants received placebo administered in 0.2 mL injections, 0.7 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.	Drug: Placebo
Experimental: Deoxycholic Acid Injection 0.2 mL/1.0 cm Participants received deoxycholic acid administered in 0.2 mL injections, 1.0 cm apart, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.	Drug: Deoxycholic Acid Injection Formulated as an injectable solution containing deoxycholic acid at a concentration of 10 mg/mL. Other Names: • ATX-101
Placebo Comparator: Placebo 0.2 mL/1.0 cm Participants received placebo administered in 0.2 mL injections, 1.0 cm apart, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.	Drug: Placebo
Experimental: Deoxycholic Acid Injection 0.4 mL/1.0 cm Participants received deoxycholic acid administered in 0.4 mL injections, 1.0 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.	Drug: Deoxycholic Acid Injection Formulated as an injectable solution containing deoxycholic acid at a concentration of 10 mg/mL. Other Names: • ATX-101
Placebo Comparator: Placebo 0.4 mL/1.0 cm Participants received placebo administered in 0.4 mL injections, 1.0 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.	Drug: Placebo

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 25 Years

Maximum Age: 65 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Submental fat that was considered undesirable by the subject and graded by the investigator as 2 or 3 using the submental fat (SMF) rating scale
- Good general health
- Signed informed consent

Exclusion Criteria:

- History of any treatment in the neck or chin area
- Loose skin or prominent platysmal bands in the neck or chin area
- Recent treatment with anticoagulants
- Presence of clinically significant health problems

Contacts/Locations

Study Officials: Frederick Beddingfield, III, M.D., Ph.D.
Study Director
Kythera Biopharmaceuticals, Inc.

Locations: Australia, Victoria
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Canada, Ontario
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Niagara Falls, Ontario, Canada, L2E 7H1

United Kingdom
Investigational Site
Manchester, United Kingdom, M68HD

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Oakville, Ontario, Canada, L6J 7W5

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Investigational Site
Sydney, Australia, 2000

Canada, Ontario
Investigational Site
Toronto, Ontario, Canada, M5S 3B4

Investigational Site
Toronto, Ontario, Canada, M4V 1R1

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	This study was conducted at 7 study centers: 4 in Canada, 2 in Australia and 1 in the United Kingdom.
Pre-Assignment Details	Participants were randomized to receive either deoxycholic acid or placebo injection in one of 3 treatment dosing regimens for a total of 6 treatment groups. Placebo participants were pooled for analysis.

Reporting Groups

	Description
Deoxycholic Acid Injection 0.2 mL/0.7 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 0.7 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.2 mL/1.0 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 1.0 cm apart, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

	Description
Deoxycholic Acid Injection 0.4 mL/1.0 cm	Participants received deoxycholic acid administered in 0.4 mL injections, 1.0 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Pooled Placebo	Participants received matching placebo administered in 0.2 or 0.4 mL injections, 0.7 or 1.0 cm apart, up to 4.8 or 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Overall Study

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
Started	24	14	21	14
Received Treatment	24	13	20	14
Completed	20	11	18	13
Not Completed	4	3	3	1
Patient Request	0	0	2	0
Inability to Complete Study Procedures	0	1	0	0
Lost to Follow-up	3	0	0	1
Non-compliance	1	1	0	0
Did Not Meet Entry Criteria	0	0	1	0
Death	0	1	0	0

Baseline Characteristics

Analysis Population Description

Safety/Modified Intent-to-Treat (mITT) subset included all randomized participants who received at least 1 dose of study material and who had at least 1 post-baseline observation

Reporting Groups

	Description
Deoxycholic Acid Injection 0.2 mL/0.7 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 0.7 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.2 mL/1.0 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 1.0 cm apart, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

	Description
Deoxycholic Acid Injection 0.4 mL/1.0 cm	Participants received deoxycholic acid administered in 0.4 mL injections, 1.0 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Pooled Placebo	Participants received matching placebo administered in 0.2 or 0.4 mL injections, 0.7 or 1.0 cm apart, up to 4.8 or 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Baseline Measures

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo	Total
Number of Participants	24	13	20	14	71
Age, Continuous [units: years] Mean (Standard Deviation)	46.5 (7.79)	45.9 (4.23)	47.0 (10.37)	49.4 (10.85)	47.1 (8.69)
Gender, Male/Female [units: participants]					
Female	19	11	15	10	55
Male	5	2	5	4	16
Race/Ethnicity, Customized White [units: participants]	24	13	20	14	71
Weight [units: kg] Mean (Standard Deviation)	78.31 (11.987)	82.10 (18.204)	90.80 (17.128)	84.78 (16.381)	83.78 (16.074)
Submental Fat (SMF) Rating [1] [units: participants]					
2	17	10	11	7	45
3	7	3	9	7	26
Fitzpatrick Skin Type [2] [units: participants]					
I - III	24	13	20	14	71
IV - VI	0	0	0	0	0

[1] SMF Ratings:

- 0 = Absent submental convexity: No localized submental fat evident;
- 1 = Mild submental convexity: Minimal, localized submental fat;
- 2 = Moderate submental convexity: Prominent, localized submental fat;

- 3 = Severe submental convexity: Marked, localized submental fat;
- 4 = Extreme submental convexity.

[2] Fitzpatrick Skin Type is a numerical classification schema for human skin color and typical response to ultraviolet (UV) light:

- Type I: Pale white skin, blue/hazel eyes, blond/red hair; Always burns, does not tan.
- Type II: Fair skin, blue eyes; Burns easily, tans poorly.
- Type III: Darker white skin; Tans after initial burn.
- Type IV: Light brown skin; Burns minimally, tans easily.
- Type V: Brown skin; Rarely burns, tans darkly easily.
- Type VI: Dark brown or black skin; Never burns, always tans darkly.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Participants With Adverse Events
Measure Description	The investigator determined the relationship of each adverse event to the administration of study drug. Severity of adverse events was determined using the following scale: • Mild: The participant is aware of a sign or symptom, but it is easily tolerated • Moderate: Discomfort or interference with usual activity • Severe: Incapacitating, with inability to engage in usual activity. A serious AE (SAE) was defined as an event that may constitute a significant medical hazard or side-effect, regardless of the investigator or sponsor's opinion regarding relatedness to study material. Serious events included, but were not limited to, any event that: • was fatal • was life-threatening • required inpatient hospitalization or prolongation of existing hospitalization • resulted in persistent or significant disability/incapacity • was a congenital anomaly/birth defect • other significant medical hazard
Time Frame	From the first dose of study drug until 12 weeks after the last dose (up to 24 weeks after first treatment).
Safety Issue?	No

Analysis Population Description
Safety/miTT subset

Reporting Groups

	Description
Deoxycholic Acid Injection 0.2 mL/0.7 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 0.7 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.2 mL/1.0 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 1.0 cm apart, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
0Deoxycholic Acid Injection 0.4 mL/1.0 cm	Participants received deoxycholic acid administered in 0.4 mL injections, 1.0 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Pooled Placebo	Participants received matching placebo administered in 0.2 or 0.4 mL injections, 0.7 or 1.0 cm apart, up to 4.8 or 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Measured Values

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	0Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
Number of Participants Analyzed	24	13	20	14
Number of Participants With Adverse Events [units: participants]				
Any adverse event	24	13	20	14
Adverse event associated with treatment area	24	13	20	14
Study drug-related adverse event	24	13	20	14
Study drug-related severe adverse event	6	0	5	0
Serious adverse event	0	1	0	0
Discontinued due to adverse event	2	1	0	0
Deaths	0	1	0	0

2. Primary Outcome Measure:

Measure Title	Number of Participants With Clinically Significant Changes From Baseline in Laboratory Values, Weight, Vital Signs, and Physical Examinations
Measure Description	
Time Frame	From the first dose of study drug until 12 weeks after the last dose (up to 24 weeks after first treatment).

Safety Issue?	No

Analysis Population Description
Safety/mITT subset

Reporting Groups

	Description
Deoxycholic Acid Injection 0.2 mL/0.7 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 0.7 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.2 mL/1.0 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 1.0 cm apart, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.4 mL/1.0 cm	Participants received deoxycholic acid administered in 0.4 mL injections, 1.0 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Pooled Placebo	Participants received matching placebo administered in 0.2 or 0.4 mL injections, 0.7 or 1.0 cm apart, up to 4.8 or 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Measured Values

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
Number of Participants Analyzed	24	13	20	14
Number of Participants With Clinically Significant Changes From Baseline in Laboratory Values, Weight, Vital Signs, and Physical Examinations [units: participants]				
Laboratory Values	3	0	2	0
Weight	0	0	0	0
Vital Signs	0	0	1	0
Physical Examinations	0	0	0	0

3. Secondary Outcome Measure:

Measure Title	Change From Baseline in Submental Fat (SMF) Rating Scale Score

Measure Description	The SMF rating scale score is based on the investigator's clinical evaluation of the participant, where submental fullness is scored on a 5-point ordinal scale (0-4) with 0 = absent, 1 = mild, 2 = moderate, 3 = severe, and 4 = extreme. A negative change from Baseline indicates improvement.
Time Frame	Baseline and 4 weeks after last treatment (up to 16 weeks after first dose)
Safety Issue?	No

Analysis Population Description

Safety/mITT subset with available data

Reporting Groups

	Description
Deoxycholic Acid Injection 0.2 mL/0.7 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 0.7 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.2 mL/1.0 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 1.0 cm apart, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.4 mL/1.0 cm	Participants received deoxycholic acid administered in 0.4 mL injections, 1.0 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Pooled Placebo	Participants received matching placebo administered in 0.2 or 0.4 mL injections, 0.7 or 1.0 cm apart, up to 4.8 or 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Measured Values

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
Number of Participants Analyzed	22	10	20	14
Change From Baseline in Submental Fat (SMF) Rating Scale Score [units: units on a scale] Mean (Standard Deviation)	-1.0 (0.58)	-1.2 (0.63)	-0.8 (0.72)	-0.4 (0.50)

Statistical Analysis 1 for Change From Baseline in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/0.7 cm, Pooled Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.005
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Based on an analysis of covariance (ANCOVA) model with treatment as the main effect and baseline SMF Rating Scale score as a covariate.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.6
	Confidence Interval	(2-Sided) 95% -1.0 to -0.2
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Change From Baseline in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/1.0 cm, Pooled Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Based on an ANCOVA model with treatment as the main effect and baseline SMF Rating Scale score as a covariate.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.9
	Confidence Interval	(2-Sided) 95% -1.4 to -0.4
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Change From Baseline in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.4 mL/1.0 cm, Pooled Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.069
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Based on an ANCOVA model with treatment as the main effect and baseline SMF Rating Scale score as a covariate.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.4
	Confidence Interval	(2-Sided) 95% -0.8 to 0.0
	Estimation Comments	[Not specified]

4. Secondary Outcome Measure:

Measure Title	Change From Baseline in Subject Satisfaction With Appearance Rating Scale
Measure Description	The Subject Satisfaction with Appearance Rating Scale assesses participants' satisfaction with their appearance in association with the face and chin on a 7-point scale from 0 to 6 where 0 = Extremely dissatisfied, 1 = Dissatisfied, 2 = Slightly dissatisfied, 3 = Neither satisfied nor dissatisfied, 4 = Slightly satisfied, 5 = Satisfied and 6 = Extremely satisfied. A positive change from Baseline indicates improvement.
Time Frame	Baseline and 4 weeks after last treatment (up to 16 weeks after first dose)
Safety Issue?	No

Analysis Population Description

Safety/mITT subset with available data

Reporting Groups

	Description
Deoxycholic Acid Injection 0.2 mL/0.7 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 0.7 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.2 mL/1.0 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 1.0 cm apart, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.4 mL/1.0 cm	Participants received deoxycholic acid administered in 0.4 mL injections, 1.0 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Pooled Placebo	Participants received matching placebo administered in 0.2 or 0.4 mL injections, 0.7 or 1.0 cm apart, up to 4.8 or 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Measured Values

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
Number of Participants Analyzed	22	10	20	14
Change From Baseline in Subject Satisfaction With Appearance Rating Scale [units: units on a scale] Mean (Standard Deviation)	3.5 (1.47)	4.3 (1.34)	2.8 (2.20)	1.8 (1.72)

Statistical Analysis 1 for Change From Baseline in Subject Satisfaction With Appearance Rating Scale

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/0.7 cm, Pooled Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.005
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Based on an ANCOVA model with treatment as the main effect and baseline SMF Rating Scale score as a covariate.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	1.8
	Confidence Interval	(2-Sided) 95% 0.6 to 3.0
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Change From Baseline in Subject Satisfaction With Appearance Rating Scale

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/1.0 cm, Pooled Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Based on an ANCOVA model with treatment as the main effect and baseline SMF Rating Scale score as a covariate.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	2.5
	Confidence Interval	(2-Sided) 95% 1.0 to 4.0
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Change From Baseline in Subject Satisfaction With Appearance Rating Scale

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.4 mL/1.0 cm, Pooled Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.122
	Comments	[Not specified]

	Method	ANCOVA
	Comments	Based on an ANCOVA model with treatment as the main effect and baseline SMF Rating Scale score as a covariate.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	1.0
	Confidence Interval	(2-Sided) 95% -0.3 to 2.2
	Estimation Comments	[Not specified]

5. Secondary Outcome Measure:

Measure Title	Percentage of Participants With a Response in the Subject Global Improvement Rating
Measure Description	Participants were asked to rate their total improvement or worsening in the appearance and physical feeling of their chin and neck area since before they received study treatment, whether or not they believed it was due to study treatment or to any other cause. 0 = Very much worse, 1 = Much worse, 2 = Minimally worse, 3 = No change, 4 = Minimally improved, 5 = Much improved, 6 = Very much improved. Response is defined as any improvement, ie, a global improvement rating of 4, 5, or 6.
Time Frame	4 weeks after last treatment (up to 16 weeks after first dose)
Safety Issue?	No

Analysis Population Description

Safety/mITT subset with available data

Reporting Groups

	Description
Deoxycholic Acid Injection 0.2 mL/0.7 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 0.7 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.2 mL/1.0 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 1.0 cm apart, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.4 mL/1.0 cm	Participants received deoxycholic acid administered in 0.4 mL injections, 1.0 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Pooled Placebo	Participants received matching placebo administered in 0.2 or 0.4 mL injections, 0.7 or 1.0 cm apart, up to 4.8 or 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Measured Values

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
Number of Participants Analyzed	22	10	20	14
Percentage of Participants With a Response in the Subject Global Improvement Rating [units: percentage of participants]	95.5	90.0	80.0	57.1

Statistical Analysis 1 for Percentage of Participants With a Response in the Subject Global Improvement Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/0.7 cm, Pooled Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.008
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Difference from Placebo]
	Estimated Value	38.3
	Confidence Interval	(2-Sided) 95% 11.0 to 65.7
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Percentage of Participants With a Response in the Subject Global Improvement Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/1.0 cm, Pooled Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.172
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference from Placebo]
	Estimated Value	32.9
	Confidence Interval	(2-Sided) 95% 1.0 to 64.8
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Percentage of Participants With a Response in the Subject Global Improvement Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.4 mL/1.0 cm, Pooled Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.252
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference from Placebo]
	Estimated Value	22.9
	Confidence Interval	(2-Sided) 95% -8.4 to 54.2
	Estimation Comments	[Not specified]

6. Secondary Outcome Measure:

Measure Title	Percentage of Participants With an SMF Response

Measure Description	Response is defined as a participant with at least a 1-grade improvement in SMF Rating Scale score at Week 16 from Baseline. The SMF rating scale score is based on the investigator's clinical evaluation of the participant, where submental fullness is scored on a 5-point ordinal scale (0-4) with 0 = absent, 1 = mild, 2 = moderate, 3 = severe, and 4 = extreme.
Time Frame	Baseline and 4 weeks after last treatment (up to 16 weeks after first dose)
Safety Issue?	No

Analysis Population Description

Safety/mITT subset with available data

Reporting Groups

	Description
Deoxycholic Acid Injection 0.2 mL/0.7 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 0.7 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.2 mL/1.0 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 1.0 cm apart, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.4 mL/1.0 cm	Participants received deoxycholic acid administered in 0.4 mL injections, 1.0 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Pooled Placebo	Participants received matching placebo administered in 0.2 or 0.4 mL injections, 0.7 or 1.0 cm apart, up to 4.8 or 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Measured Values

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
Number of Participants Analyzed	22	10	20	14
Percentage of Participants With an SMF Response [units: percentage of participants]	81.8	90.0	60.0	35.7

Statistical Analysis 1 for Percentage of Participants With an SMF Response

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/0.7 cm, Pooled Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.011
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference from Placebo]
	Estimated Value	46.1
	Confidence Interval	(2-Sided) 95% 16.3 to 75.9
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Percentage of Participants With an SMF Response

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/1.0 cm, Pooled Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.013
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference from Placebo]
	Estimated Value	54.3
	Confidence Interval	(2-Sided) 95% 23.0 to 85.5
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Percentage of Participants With an SMF Response

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.4 mL/1.0 cm, Pooled Placebo
	Comments	[Not specified]

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.296
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference from Placebo]
	Estimated Value	24.3
	Confidence Interval	(2-Sided) 95% -8.7 to 57.3
	Estimation Comments	[Not specified]

7. Secondary Outcome Measure:

Measure Title	Change From Baseline in Skin Laxity Rating
Measure Description	Skin laxity assessment was based on clinical evaluation and palpation of the submental area on the following scale: 1 = no laxity; 2 = minimal laxity; 3 = moderate laxity; 4 = very lax. A negative change from Baseline indicates improvement.
Time Frame	Baseline and Week 4, Week 8, Week 12, Week 16 (4 weeks after last treatment) and Week 24 (12 weeks after last treatment)
Safety Issue?	No

Analysis Population Description
Safety/mITT subset

Reporting Groups

	Description
Deoxycholic Acid Injection 0.2 mL/0.7 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 0.7 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.2 mL/1.0 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 1.0 cm apart, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

	Description
Deoxycholic Acid Injection 0.4 mL/1.0 cm	Participants received deoxycholic acid administered in 0.4 mL injections, 1.0 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Pooled Placebo	Participants received matching placebo administered in 0.2 or 0.4 mL injections, 0.7 or 1.0 cm apart, up to 4.8 or 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Measured Values

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
Number of Participants Analyzed	24	13	20	14
Change From Baseline in Skin Laxity Rating [units: units on a scale] Mean (Standard Deviation)				
Week 4	-0.1 (0.34)	-0.1 (0.64)	-0.2 (0.54)	0.0 (0.78)
Week 8	-0.2 (0.59)	0.1 (0.30)	-0.1 (0.57)	-0.1 (0.66)
Week 12	-0.1 (0.51)	-0.2 (0.39)	-0.2 (0.71)	-0.1 (0.53)
Week 16	-0.2 (0.60)	-0.3 (0.48)	-0.2 (0.59)	-0.1 (0.53)
Week 24	-0.2 (0.68)	-0.4 (0.67)	-0.1 (0.66)	-0.2 (0.55)

Statistical Analysis 1 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/0.7 cm, Pooled Placebo
	Comments	Week 4
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.460
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.1
	Confidence Interval	(2-Sided) 95% -0.5 to 0.2
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/1.0 cm, Pooled Placebo
	Comments	Week 4
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.906
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	0.0
	Confidence Interval	(2-Sided) 95% -0.5 to 0.4
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.4 mL/1.0 cm, Pooled Placebo
	Comments	Week 4
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.404
	Comments	[Not specified]

	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.2
	Confidence Interval	(2-Sided) 95% -0.6 to 0.2
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/0.7 cm, Pooled Placebo
	Comments	Week 8
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.791
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.1
	Confidence Interval	(2-Sided) 95% -0.5 to 0.3
	Estimation Comments	[Not specified]

Statistical Analysis 5 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/1.0 cm, Pooled Placebo
	Comments	Week 8
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.410
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	0.2
	Confidence Interval	(2-Sided) 95% -0.3 to 0.6
	Estimation Comments	[Not specified]

Statistical Analysis 6 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.4 mL/1.0 cm, Pooled Placebo
	Comments	Week 8
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.733
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	0.1
	Confidence Interval	(2-Sided) 95% -0.3 to 0.5
	Estimation Comments	[Not specified]

Statistical Analysis 7 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/0.7 cm, Pooled Placebo
	Comments	Week 12
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.542
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.
Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	0.1
	Confidence Interval	(2-Sided) 95% -0.3 to 0.5
	Estimation Comments	[Not specified]

Statistical Analysis 8 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/1.0 cm, Pooled Placebo
	Comments	Week 12
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.882
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.
Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	0.0

	Confidence Interval	(2-Sided) 95% -0.4 to 0.5
	Estimation Comments	[Not specified]

Statistical Analysis 9 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.4 mL/1.0 cm, Pooled Placebo
	Comments	Week 12
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.934
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.
Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	0.0
	Confidence Interval	(2-Sided) 95% -0.4 to 0.4
	Estimation Comments	[Not specified]

Statistical Analysis 10 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/0.7 cm, Pooled Placebo
	Comments	Week 16
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.838
	Comments	[Not specified]
	Method	Other [Repeated Measures]

	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	0.0
	Confidence Interval	(2-Sided) 95% -0.4 to 0.4
	Estimation Comments	[Not specified]

Statistical Analysis 11 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/1.0 cm, Pooled Placebo
	Comments	Week 16
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.777
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.1
	Confidence Interval	(2-Sided) 95% -0.5 to 0.4
	Estimation Comments	[Not specified]

Statistical Analysis 12 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.4 mL/1.0 cm, Pooled Placebo
	Comments	Week 16
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.795
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	0.1
	Confidence Interval	(2-Sided) 95% -0.4 to 0.5
	Estimation Comments	[Not specified]

Statistical Analysis 13 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/0.7 cm, Pooled Placebo
	Comments	Week 24
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.852
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS mean Difference]
	Estimated Value	0.0
	Confidence Interval	(2-Sided) 95% -0.4 to 0.4
	Estimation Comments	[Not specified]

Statistical Analysis 14 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/1.0 cm, Pooled Placebo
	Comments	Week 24

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.444
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.2
	Confidence Interval	(2-Sided) 95% -0.6 to 0.3
	Estimation Comments	[Not specified]

Statistical Analysis 15 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.4 mL/1.0 cm, Pooled Placebo
	Comments	Week 24
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.724
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	0.1
	Confidence Interval	(2-Sided) 95% -0.3 to 0.5
	Estimation Comments	[Not specified]

8. Secondary Outcome Measure:

Measure Title	Change From Baseline to Each Visit in Submental Fat (SMF) Rating Scale Score
Measure Description	The SMF rating scale score is based on the investigator's clinical evaluation of the participant, where submental fullness is scored on a 5-point ordinal scale (0-4) with 0 = absent, 1 = mild, 2 = moderate, 3 = severe, and 4 = extreme. A negative change from Baseline indicates improvement.
Time Frame	Baseline and Week 4, Week 8, Week 12, Week 16 (4 weeks after last treatment) and Week 24 (12 weeks after last treatment)
Safety Issue?	No

Analysis Population Description

Safety/mITT subset

Reporting Groups

	Description
Deoxycholic Acid Injection 0.2 mL/0.7 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 0.7 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.2 mL/1.0 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 1.0 cm apart, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.4 mL/1.0 cm	Participants received deoxycholic acid administered in 0.4 mL injections, 1.0 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Pooled Placebo	Participants received matching placebo administered in 0.2 or 0.4 mL injections, 0.7 or 1.0 cm apart, up to 4.8 or 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Measured Values

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
Number of Participants Analyzed	24	13	20	14
Change From Baseline to Each Visit in Submental Fat (SMF) Rating Scale Score [units: units on a scale] Mean (Standard Deviation)				
Week 4	-0.3 (0.57)	-0.5 (0.52)	-0.1 (0.32)	-0.3 (0.47)
Week 8	-0.6 (0.67)	-0.6 (0.67)	-0.5 (0.61)	-0.4 (0.50)
Week 12	-0.9 (0.59)	-1.0 (0.74)	-0.7 (0.59)	-0.4 (0.51)

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
Week 16	-1.0 (0.58)	-1.2 (0.63)	-0.8 (0.72)	-0.4 (0.50)
Week 24	-1.0 (0.45)	-1.2 (0.87)	-1.0 (0.67)	-0.4 (0.51)

Statistical Analysis 1 for Change From Baseline to Each Visit in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/0.7 cm, Pooled Placebo
	Comments	Week 4
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.934
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	0.0
	Confidence Interval	(2-Sided) 95% -0.4 to 0.4
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Change From Baseline to Each Visit in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/1.0 cm, Pooled Placebo
	Comments	Week 4
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.286
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.2
	Confidence Interval	(2-Sided) 95% -0.7 to 0.2
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Change From Baseline to Each Visit in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.4 mL/1.0 cm, Pooled Placebo
	Comments	Week 4
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.190
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	0.3
	Confidence Interval	(2-Sided) 95% -0.1 to 0.7
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Change From Baseline to Each Visit in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/0.7 cm, Pooled Placebo
	Comments	Week 8

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.402
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.2
	Confidence Interval	(2-Sided) 95% -0.5 to 0.2
	Estimation Comments	[Not specified]

Statistical Analysis 5 for Change From Baseline to Each Visit in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/1.0 cm, Pooled Placebo
	Comments	Week 8
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.290
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.2
	Confidence Interval	(2-Sided) 95% -0.7 to 0.2
	Estimation Comments	[Not specified]

Statistical Analysis 6 for Change From Baseline to Each Visit in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.4 mL/1.0 cm, Pooled Placebo
	Comments	Week 8
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.863
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.
Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	0.0
	Confidence Interval	(2-Sided) 95% -0.4 to 0.4
	Estimation Comments	[Not specified]

Statistical Analysis 7 for Change From Baseline to Each Visit in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/0.7 cm, Pooled Placebo
	Comments	Week 12
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.128
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.
Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.3

	Confidence Interval	(2-Sided) 95% -0.7 to 0.1
	Estimation Comments	[Not specified]

Statistical Analysis 8 for Change From Baseline to Each Visit in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/1.0 cm, Pooled Placebo
	Comments	Week 12
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.018
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.
Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.5
	Confidence Interval	(2-Sided) 95% -0.9 to -0.1
	Estimation Comments	[Not specified]

Statistical Analysis 9 for Change From Baseline to Each Visit in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.4 mL/1.0 cm, Pooled Placebo
	Comments	Week 12
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.489
	Comments	[Not specified]
	Method	Other [Repeated Measures]

	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.1
	Confidence Interval	(2-Sided) 95% -0.5 to 0.3
	Estimation Comments	[Not specified]

Statistical Analysis 10 for Change From Baseline to Each Visit in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/0.7 cm, Pooled Placebo
	Comments	Week 16
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.007
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.5
	Confidence Interval	(2-Sided) 95% -0.9 to -0.1
	Estimation Comments	[Not specified]

Statistical Analysis 11 for Change From Baseline to Each Visit in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/1.0 cm, Pooled Placebo
	Comments	Week 16
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.8
	Confidence Interval	(2-Sided) 95% -1.3 to -0.4
	Estimation Comments	[Not specified]

Statistical Analysis 12 for Change From Baseline to Each Visit in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.4 mL/1.0 cm, Pooled Placebo
	Comments	Week 16
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.122
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.3
	Confidence Interval	(2-Sided) 95% -0.7 to 0.1
	Estimation Comments	[Not specified]

Statistical Analysis 13 for Change From Baseline to Each Visit in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/0.7 cm, Pooled Placebo
	Comments	Week 24

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.005
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.6
	Confidence Interval	(2-Sided) 95% -0.9 to -0.2
	Estimation Comments	[Not specified]

Statistical Analysis 14 for Change From Baseline to Each Visit in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/1.0 cm, Pooled Placebo
	Comments	Week 24
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.8
	Confidence Interval	(2-Sided) 95% -1.2 to -0.3
	Estimation Comments	[Not specified]

Statistical Analysis 15 for Change From Baseline to Each Visit in Submental Fat (SMF) Rating Scale Score

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.4 mL/1.0 cm, Pooled Placebo
	Comments	Week 24
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.007
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Based on repeated measures analysis of variance with treatment, visit, center, treatment x visit as fixed effects and subject as a random effect.
Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.6
	Confidence Interval	(2-Sided) 95% -1.0 to -0.2
	Estimation Comments	[Not specified]

9. Secondary Outcome Measure:

Measure Title	Change From Baseline in the Cervicomental Angle
Measure Description	The cervicomental angle was measured using a profile view photograph obtained at each visit. A goniometer was used to determine the angle. Cervicomental angle measurements less than 80 degrees are excluded, due to error in measurement.
Time Frame	Baseline and 4 weeks after last treatment (up to 16 weeks after first dose)
Safety Issue?	No

Analysis Population Description

Safety/mITT subset with available data

Reporting Groups

	Description
Deoxycholic Acid Injection 0.2 mL/0.7 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 0.7 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

	Description
Deoxycholic Acid Injection 0.2 mL/1.0 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 1.0 cm apart, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.4 mL/1.0 cm	Participants received deoxycholic acid administered in 0.4 mL injections, 1.0 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Pooled Placebo	Participants received matching placebo administered in 0.2 or 0.4 mL injections, 0.7 or 1.0 cm apart, up to 4.8 or 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Measured Values

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
Number of Participants Analyzed	22	10	20	13
Change From Baseline in the Cervicomental Angle [units: degrees] Mean (Standard Deviation)	-5.0 (9.85)	-1.5 (7.84)	-1.5 (10.40)	-2.7 (7.80)

Statistical Analysis 1 for Change From Baseline in the Cervicomental Angle

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/0.7 cm, Pooled Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.573
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Based on an ANCOVA model with treatment as the main effect and baseline SMF Rating Scale score as a covariate.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-1.9
	Confidence Interval	(2-Sided) 95% -8.6 to 4.8

	Estimation Comments	[Not specified]

Statistical Analysis 2 for Change From Baseline in the Cervicomental Angle

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.2 mL/1.0 cm, Pooled Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.653
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Based on an ANCOVA model with treatment as the main effect and baseline SMF Rating Scale score as a covariate.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	1.8
	Confidence Interval	(2-Sided) 95% -6.3 to 9.9
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Change From Baseline in the Cervicomental Angle

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 0.4 mL/1.0 cm, Pooled Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.688
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Based on an ANCOVA model with treatment as the main effect and baseline SMF Rating Scale score as a covariate.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	1.4
	Confidence Interval	(2-Sided) 95% -5.4 to 8.1
	Estimation Comments	[Not specified]

10. Secondary Outcome Measure:

Measure Title	Visual Analogue Scale Pain Intensity Rating
Measure Description	Participants rated pain associated with the submental area on a 100 mm horizontal axis ranging from 0 (no pain) to 100 (most severe pain possible)
Time Frame	Approximately 60 minutes after completion of each treatment session at Week 0, Week 4, Week 8 and Week 12
Safety Issue?	No

Analysis Population Description

Safety/mITT subset with available data at each time point (indicated by "N")

Reporting Groups

	Description
Deoxycholic Acid Injection 0.2 mL/0.7 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 0.7 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.2 mL/1.0 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 1.0 cm apart, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.4 mL/1.0 cm	Participants received deoxycholic acid administered in 0.4 mL injections, 1.0 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Pooled Placebo	Participants received matching placebo administered in 0.2 or 0.4 mL injections, 0.7 or 1.0 cm apart, up to 4.8 or 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Measured Values

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
Number of Participants Analyzed	24	13	20	14
Visual Analogue Scale Pain Intensity Rating [units: units on a scale] Mean (Standard Deviation)				

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
Treatment 1 (N=24, 12, 20, 14)	33.0 (27.29)	25.8 (16.19)	41.9 (27.50)	17.1 (19.03)
Treatment 2 (N=19, 10, 16, 14)	27.9 (27.69)	38.2 (26.62)	31.1 (31.00)	24.9 (28.73)
Treatment 3 (N=17, 10, 16, 13)	26.5 (28.50)	19.2 (25.35)	22.6 (30.77)	20.7 (27.21)
Treatment 4 (N=14, 10, 15, 14)	14.0 (18.68)	13.7 (14.55)	19.0 (24.74)	16.7 (27.27)

Reported Adverse Events

Time Frame	From the first dose of study drug until 12 weeks after the last dose (up to 24 weeks after first treatment).
Additional Description	[Not specified]

Reporting Groups

	Description
Deoxycholic Acid Injection 0.2 mL/0.7 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 0.7 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.2 mL/1.0 cm	Participants received deoxycholic acid administered in 0.2 mL injections, 1.0 cm apart, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 0.4 mL/1.0 cm	Participants received deoxycholic acid administered in 0.4 mL injections, 1.0 cm apart, up to 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Pooled Placebo	Participants received matching placebo administered in 0.2 or 0.4 mL injections, 0.7 or 1.0 cm apart, up to 4.8 or 9.6 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Serious Adverse Events

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)
Cardiac disorders				
Cardiac Arrest [A] †	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Bile Duct Cancer [A] †	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 11.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	24/24 (100%)	13/13 (100%)	20/20 (100%)	14/14 (100%)
Blood and lymphatic system disorders				
Anaemia [A] †	0/24 (0%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Neutropenia [A] †	0/24 (0%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Ear and labyrinth disorders				
Ear Pain [A] †	0/24 (0%)	0/13 (0%)	0/20 (0%)	1/14 (7.14%)
Eye disorders				
Eye Swelling [A] †	0/24 (0%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Gastrointestinal disorders				
Dyspepsia [A] †	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)
Dysphagia [A] †	1/24 (4.17%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Faeces Pale [A] †	1/24 (4.17%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)
Gastrooesophageal Reflux Disease [A] †	0/24 (0%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Nausea [A] †	0/24 (0%)	1/13 (7.69%)	2/20 (10%)	0/14 (0%)
General disorders				

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Fatigue [A] †	0/24 (0%)	0/13 (0%)	1/20 (5%)	1/14 (7.14%)
Injection Site Anaesthesia [A] †	21/24 (87.5%)	12/13 (92.31%)	16/20 (80%)	6/14 (42.86%)
Injection Site Bruising [A] †	17/24 (70.83%)	13/13 (100%)	15/20 (75%)	12/14 (85.71%)
Injection Site Discolouration [A] †	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)
Injection Site Discomfort [A] †	1/24 (4.17%)	0/13 (0%)	1/20 (5%)	1/14 (7.14%)
Injection Site Erythema [A] †	12/24 (50%)	3/13 (23.08%)	9/20 (45%)	4/14 (28.57%)
Injection Site Haemorrhage [A] †	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)
Injection Site Induration [A] †	18/24 (75%)	9/13 (69.23%)	16/20 (80%)	5/14 (35.71%)
Injection Site Nodule [A] †	2/24 (8.33%)	1/13 (7.69%)	3/20 (15%)	1/14 (7.14%)
Injection Site Oedema [A] †	5/24 (20.83%)	1/13 (7.69%)	4/20 (20%)	2/14 (14.29%)
Injection Site Pain [A] †	22/24 (91.67%)	13/13 (100%)	18/20 (90%)	10/14 (71.43%)
Injection Site Papule [A] †	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)
Injection Site Pruritus [A] †	4/24 (16.67%)	2/13 (15.38%)	5/20 (25%)	0/14 (0%)
Injection Site Rash [A] †	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)
Injection Site Reaction [A] †	2/24 (8.33%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Injection Site Swelling [A] †	14/24 (58.33%)	10/13 (76.92%)	13/20 (65%)	11/14 (78.57%)
Injection Site Vesicles [A] †	0/24 (0%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Injection Site Warmth [A] †	1/24 (4.17%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Malaise [A] †	0/24 (0%)	0/13 (0%)	0/20 (0%)	1/14 (7.14%)
Pain [A] †	0/24 (0%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Pyrexia [A] †	0/24 (0%)	0/13 (0%)	0/20 (0%)	1/14 (7.14%)

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Infections and infestations				
Bronchitis [A] †	0/24 (0%)	0/13 (0%)	0/20 (0%)	1/14 (7.14%)
Eye Infection [A] †	0/24 (0%)	0/13 (0%)	0/20 (0%)	1/14 (7.14%)
Folliculitis [A] †	0/24 (0%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Lower Respiratory Tract Infection [A] †	1/24 (4.17%)	0/13 (0%)	0/20 (0%)	2/14 (14.29%)
Nasopharyngitis [A] †	0/24 (0%)	0/13 (0%)	2/20 (10%)	3/14 (21.43%)
Streptococcal Bacteraemia [A] †	0/24 (0%)	0/13 (0%)	0/20 (0%)	1/14 (7.14%)
Tonsillitis [A] †	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)
Tooth Abscess [A] †	0/24 (0%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Upper Respiratory Tract Infection [A] †	0/24 (0%)	0/13 (0%)	0/20 (0%)	2/14 (14.29%)
Urinary Tract Infection [A] †	0/24 (0%)	0/13 (0%)	0/20 (0%)	1/14 (7.14%)
Vaginal Infection [A] †	0/24 (0%)	0/13 (0%)	0/20 (0%)	1/14 (7.14%)
Injury, poisoning and procedural complications				
Arthropod Bite [A] †	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)
Limb Injury [A] †	0/24 (0%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Periorbital haematoma [A] †	0/24 (0%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Investigations				
Blood Glucose Increased [A] †	1/24 (4.17%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Blood Pressure Increased [A] †	0/24 (0%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A] †	1/24 (4.17%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Arthritis [A] †	0/24 (0%)	0/13 (0%)	1/20 (5%)	0/14 (0%)

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Joint Stiffness [A] †	0/24 (0%)	0/13 (0%)	0/20 (0%)	1/14 (7.14%)
Muscle Spasms [A] †	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)
Musculoskeletal Pain [A] †	1/24 (4.17%)	1/13 (7.69%)	0/20 (0%)	1/14 (7.14%)
Myalgia [A] †	0/24 (0%)	0/13 (0%)	0/20 (0%)	1/14 (7.14%)
Pain In Extremity [A] †	1/24 (4.17%)	1/13 (7.69%)	1/20 (5%)	1/14 (7.14%)
Nervous system disorders				
Dizziness [A] †	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)
Headache [A] †	3/24 (12.5%)	1/13 (7.69%)	3/20 (15%)	4/14 (28.57%)
Migraine [A] †	0/24 (0%)	0/13 (0%)	0/20 (0%)	1/14 (7.14%)
Renal and urinary disorders				
Chromaturia [A] †	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)
Reproductive system and breast disorders				
Dysmenorrhoea [A] †	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)
Premenstrual Syndrome [A] †	0/24 (0%)	0/13 (0%)	0/20 (0%)	1/14 (7.14%)
Respiratory, thoracic and mediastinal disorders				
Asthma [A] †	0/24 (0%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Bronchospasm [A] †	0/24 (0%)	0/13 (0%)	0/20 (0%)	1/14 (7.14%)
Cough [A] †	0/24 (0%)	0/13 (0%)	0/20 (0%)	1/14 (7.14%)
Dysphonia [A] †	0/24 (0%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Productive Cough [A] †	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)
Sinus Congestion [A] †	2/24 (8.33%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Skin and subcutaneous tissue disorders				

	Deoxycholic Acid Injection 0.2 mL/0.7 cm	Deoxycholic Acid Injection 0.2 mL/1.0 cm	Deoxycholic Acid Injection 0.4 mL/1.0 cm	Pooled Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Alopecia [A] †	0/24 (0%)	0/13 (0%)	1/20 (5%)	0/14 (0%)
Hair Growth Abnormal [A] †	0/24 (0%)	0/13 (0%)	0/20 (0%)	1/14 (7.14%)
Hyperhidrosis [A] †	1/24 (4.17%)	0/13 (0%)	0/20 (0%)	1/14 (7.14%)
Pruritus [A] †	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)
Rash [A] †	0/24 (0%)	1/13 (7.69%)	1/20 (5%)	0/14 (0%)
Rosacea [A] †	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)
Vascular disorders				
Haemorrhage [A] †	0/24 (0%)	1/13 (7.69%)	0/20 (0%)	0/14 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 11.0

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The Clinical Study Agreement requires that the investigator or institution obtain written consent from Kythera prior to presenting and/or publishing results of this study.

Results Point of Contact:

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