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

ClinicalTrials.gov ID: NCT00618722

Study Identification

Unique Protocol ID:	ATX-101-06-03
Brief Title:	Phase 1-2 Study of Deoxycholic Acid Injection (ATX-101) for the Reduction of Submental Fat
Official Title:	Phase 1-2, Multicenter, Randomized, Placebo-Controlled, Parallel-Group Study of the Safety and Efficacy of ATX-101 (Sodium Deoxycholate for Injection) for the Reduction of Subcutaneous Fat in the Submental Area
Secondary IDs:	2007-000146-13 [EudraCT Number]

Study Status

Record Verification:	June 2015
Overall Status:	Completed
Study Start:	August 2007
Primary Completion:	October 2008 [Actual]
Study Completion:	October 2008 [Actual]

Sponsor/Collaborators

Sponsor:	Kythera Biopharmaceuticals
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No
IND/IDE Protocol?:	No

Review Board:	Approval Status: Approved Approval Number: 08/01/2007 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

Study Description

Brief Summary:	To evaluate the safety and potential efficacy of deoxycholic acid injection compared to placebo for the reduction of submental fat (fat below the chin).
Detailed Description:	The trial included an initial cohort (3 participants in each arm) to evaluate safety followed by expansion to a second, larger cohort if adequate safety was determined in the initial cohort. Data from both cohorts was pooled for analysis.

Conditions

Conditions:	Moderate or Severe Submental Fullness
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 1/Phase 2
Intervention Model:	Parallel Assignment
Number of Arms:	4
Masking:	Double Blind (Subject, Investigator)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	85 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Deoxycholic Acid Injection 1 mg/cm² Participants received 0.5% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (1 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.	Drug: Deoxycholic Acid Injection Other Names: • ATX-101
Experimental: Deoxycholic acid Injection 2 mg/cm² Participants received 1.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (2 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.	Drug: Deoxycholic Acid Injection Other Names: • ATX-101
Experimental: Deoxycholic acid Injection 4 mg/cm² Participants received 2.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (4 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.	Drug: Deoxycholic Acid Injection Other Names: • ATX-101
Placebo Comparator: Placebo Participants received placebo administered in 0.2 mL injections, up to 4.8 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 (SMF) that was considered undesirable by the subject and graded by the investigator as 2 or 3 using the 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, MD. PhD
Study Director
Kythera Biopharmaceuticals, Inc.

Locations: Australia
Investigational Site
Toorak, Australia

Investigational Site
Carina Heights, Australia

United Kingdom
Investigational Site
London, United Kingdom

Canada
Investigational Site
Niagara Falls, Canada

Canada, Ontario
Investigational Site
Oakville, Ontario, Canada

Australia
Investigational Site
Gold Coast, Australia

References

Citations:

Links:

Study Data/Documents:

Participant Flow

Recruitment Details	The study was conducted at 6 study centers: 1 in the United Kingdom, 2 in Canada, and 3 in Australia.
Pre-Assignment Details	Enrollment was conducted in 2 stages, an initial cohort in which preliminary safety and tolerability were evaluated and a second cohort (contingent cohort), which was enrolled after it had been determined that acceptable safety and tolerability were observed in the initial cohort. Participants from both cohorts were pooled for analysis.

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received 0.5% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (1 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 2 mg/cm²	Participants received 1.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (2 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 4 mg/cm²	Participants received 2.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (4 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Placebo	Participants received placebo administered in 0.2 mL injections, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Overall Study

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Deoxycholic Acid Injection 4 mg/cm²	Placebo
Started	21	20	22	22
Received Treatment	20	20	22	22
Completed	18	18	19	18
Not Completed	3	2	3	4
Refusal of Treatment	0	0	1	0
Patient Request	1	1	1	1
Inability to Complete Study Procedure	0	1	0	0
Lost to Follow-up	2	0	0	2
Miscellaneous Reasons	0	0	1	1

Baseline Characteristics

Analysis Population Description
Safety analysis set

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received 0.5% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (1 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 2 mg/cm²	Participants received 1.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (2 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 4 mg/cm²	Participants received 2.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (4 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Placebo	Participants received placebo administered in 0.2 mL injections, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Baseline Measures

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Deoxycholic Acid Injection 4 mg/cm²	Placebo	Total
Number of Participants	20	20	22	22	84
Age, Continuous [units: years] Mean (Standard Deviation)	43.9 (9.71)	45.5 (7.37)	44.4 (6.95)	48.0 (9.78)	45.5 (8.55)
Gender, Male/Female [units: participants]					
Female	16	16	11	13	56
Male	4	4	11	9	28
Race/Ethnicity, Customized [units: participants]					
White	20	19	22	21	82
Black	0	0	0	0	0
Hispanic	0	0	0	1	1
Asian	0	0	0	0	0
Other	0	1	0	0	1

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Deoxycholic Acid Injection 4 mg/cm²	Placebo	Total
Weight [units: kg] Mean (Standard Deviation)	77.56 (14.022)	68.53 (12.472)	79.28 (12.950)	80.13 (11.083)	76.53 (13.239)
Submental Fat (SMF) Rating [1] [units: participants]					
2	13	12	13	13	51
3	7	8	9	9	33
Fitzpatrick Skin Type [2] [units: participants]					
I-III	20	20	22	22	84
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 and Modified Intent to Treat (mITT) population including all randomized participants who received at least 1 dose of study drug and who had at least 1 post-baseline observation.

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received 0.5% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (1 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 2 mg/cm²	Participants received 1.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (2 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 4 mg/cm²	Participants received 2.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (4 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Placebo	Participants received placebo administered in 0.2 mL injections, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Measured Values

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Deoxycholic Acid Injection 4 mg/cm²	Placebo
Number of Participants Analyzed	20	20	22	22
Number of Participants With Adverse Events				

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Deoxycholic Acid Injection 4 mg/cm²	Placebo
[units: participants]				
Any adverse event	20	19	22	21
Adverse event associated with treatment area	20	19	21	20
Study drug-related adverse event	20	19	21	20
Severe adverse event	0	3	3	1
Study drug-related severe adverse event	0	1	2	0
Serious adverse event	0	0	0	0
Discontinued due to adverse event	0	0	0	0
Deaths	0	0	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 population

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received 0.5% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (1 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 2 mg/cm²	Participants received 1.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (2 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 4 mg/cm²	Participants received 2.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (4 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Placebo	Participants received placebo administered in 0.2 mL injections, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Measured Values

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Deoxycholic Acid Injection 4 mg/cm²	Placebo
Number of Participants Analyzed	20	20	22	22
Number of Participants With Clinically Significant Changes From Baseline in Laboratory Values, Weight, Vital Signs, and Physical Examinations [units: participants]				
Laboratory Values	0	0	1	0
Weight	0	0	0	0
Vital Signs	0	0	0	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 population with available data

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received 0.5% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (1 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 2 mg/cm²	Participants received 1.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (2 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 4 mg/cm²	Participants received 2.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (4 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

	Description
Placebo	Participants received placebo administered in 0.2 mL injections, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Measured Values

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Deoxycholic Acid Injection 4 mg/cm²	Placebo
Number of Participants Analyzed	17	19	19	20
Change From Baseline in Submental Fat (SMF) Rating Scale Score [units: units on a scale] Mean (Standard Deviation)	-0.9 (0.70)	-0.8 (0.60)	-0.7 (0.75)	-0.5 (0.60)

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

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 1 mg/cm², Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.043
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Based on analysis of covariance (ANCOVA) model with treatment as fixed effect and baseline SMF rating as covariate.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	-0.4
	Confidence Interval	(2-Sided) 95% -0.9 to 0.0
	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 2 mg/cm², Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.050
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Based on analysis of covariance (ANCOVA) model with treatment as fixed effect and baseline SMF rating as 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]

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

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 4 mg/cm², Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.249
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Based on analysis of covariance (ANCOVA) model with treatment as fixed effect and baseline SMF rating as covariate.
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]

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 population with available data

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received 0.5% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (1 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 2 mg/cm²	Participants received 1.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (2 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 4 mg/cm²	Participants received 2.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (4 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Placebo	Participants received placebo administered in 0.2 mL injections, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Measured Values

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Deoxycholic Acid Injection 4 mg/cm²	Placebo
Number of Participants Analyzed	17	18	18	20
Change From Baseline in Subject Satisfaction With Appearance Rating Scale [units: units on a scale] Mean (Standard Deviation)	3.8 (1.85)	3.3 (1.78)	3.5 (1.42)	1.9 (2.29)

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

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 1 mg/cm², Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.003
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Based on analysis of covariance (ANCOVA) model with treatment as fixed effect and baseline SMF rating as covariate.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	1.9
	Confidence Interval	(2-Sided) 95% 0.7 to 3.1
	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 2 mg/cm², Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.030
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Based on analysis of covariance (ANCOVA) model with treatment as fixed effect and baseline SMF rating as covariate.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	1.4
	Confidence Interval	(2-Sided) 95% 0.1 to 2.6
	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 4 mg/cm², Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.012
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Based on analysis of covariance (ANCOVA) model with treatment as fixed effect and baseline SMF rating as covariate.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	1.6
	Confidence Interval	(2-Sided) 95% 0.4 to 2.8
	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 population

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received 0.5% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (1 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 2 mg/cm²	Participants received 1.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (2 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 4 mg/cm²	Participants received 2.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (4 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Placebo	Participants received placebo administered in 0.2 mL injections, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Measured Values

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Deoxycholic Acid Injection 4 mg/cm²	Placebo
Number of Participants Analyzed	20	20	22	22
Percentage of Participants With a Response in the Subject Global Improvement Rating [units: percentage of participants]	88.9	78.9	94.7	50.0

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

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 1 mg/cm², Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.015
	Comments	[Not specified]

	Method	Fisher Exact
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference from Placebo]
	Estimated Value	38.9
	Confidence Interval	(2-Sided) 95% 12.6 to 65.2
	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 2 mg/cm², Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.096
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference from Placebo]
	Estimated Value	28.9
	Confidence Interval	(2-Sided) 95% 0.4 to 57.5
	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 4 mg/cm², Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.003
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference from Placebo]
	Estimated Value	44.7
	Confidence Interval	(2-Sided) 95% 20.6 to 68.8
	Estimation Comments	[Not specified]

6. 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 population with available data

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received 0.5% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (1 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 2 mg/cm²	Participants received 1.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (2 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 4 mg/cm²	Participants received 2.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (4 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Placebo	Participants received placebo administered in 0.2 mL injections, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Measured Values

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Deoxycholic Acid Injection 4 mg/cm²	Placebo
Number of Participants Analyzed	20	20	22	22
Change From Baseline in Skin Laxity Rating [units: units on a scale] Least Squares Mean (95% Confidence Interval)				
Week 4	0.1 (-0.1 to 0.3)	-0.1 (-0.4 to 0.1)	0.0 (-0.2 to 0.3)	-0.2 (-0.4 to 0.0)
Week 8	0.1 (-0.1 to 0.4)	-0.1 (-0.4 to 0.1)	0.1 (-0.1 to 0.3)	-0.1 (-0.4 to 0.1)
Week 12	0.1 (-0.1 to 0.3)	0.1 (-0.2 to 0.3)	0.0 (-0.2 to 0.2)	-0.3 (-0.5 to -0.1)
Week 16	0.1 (-0.2 to 0.3)	-0.2 (-0.4 to 0.0)	0.0 (-0.2 to 0.2)	0.0 (-0.3 to 0.2)
Week 24	0.1 (-0.2 to 0.3)	-0.3 (-0.5 to 0.0)	0.0 (-0.2 to 0.2)	-0.1 (-0.4 to 0.1)

Statistical Analysis 1 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 1 mg/cm², Placebo
	Comments	Week 4
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.078
	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% 0.0 to 0.6
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 2 mg/cm², Placebo
	Comments	Week 4
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.781
	Comments	[Not specified]
	Method	Other [Repeated easures]
	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% -0.3 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 4 mg/cm², Placebo
	Comments	Week 4
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.146
	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% -0.1 to 0.5
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 1 mg/cm², Placebo
	Comments	Week 8
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.076
	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% 0.0 to 0.6
	Estimation Comments	[Not specified]

Statistical Analysis 5 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 2 mg/cm², Placebo
	Comments	Week 8
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.975
	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% -0.3 to 0.3
	Estimation Comments	[Not specified]

Statistical Analysis 6 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 4 mg/cm², Placebo
	Comments	Week 8
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.183
	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% -0.1 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 1 mg/cm², Placebo
	Comments	Week 12
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.017
	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	0.4
	Confidence Interval	(2-Sided) 95% 0.1 to 0.7
	Estimation Comments	[Not specified]

Statistical Analysis 8 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 2 mg/cm², Placebo
	Comments	Week 12
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.022
	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	0.4
	Confidence Interval	(2-Sided) 95% 0.1 to 0.7
	Estimation Comments	[Not specified]

Statistical Analysis 9 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 4 mg/cm², Placebo
	Comments	Week 12

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

Statistical Test of Hypothesis	P-Value	0.081
	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% 0.0 to 0.6
	Estimation Comments	[Not specified]

Statistical Analysis 10 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 1 mg/cm², Placebo
	Comments	Week 16
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.510
	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% -0.2 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 2 mg/cm², Placebo
	Comments	Week 16
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.330
	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 12 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 4 mg/cm², Placebo
	Comments	Week 16
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.720
	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 0.4
	Estimation Comments	[Not specified]

Statistical Analysis 13 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 1 mg/cm², Placebo
	Comments	Week 24
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.205
	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% -0.1 to 0.5
	Estimation Comments	[Not specified]

Statistical Analysis 14 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 2 mg/cm², Placebo
	Comments	Week 24
	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	-0.1
	Confidence Interval	(2-Sided) 95% -0.5 to 0.2
	Estimation Comments	[Not specified]

Statistical Analysis 15 for Change From Baseline in Skin Laxity Rating

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 4 mg/cm², Placebo
	Comments	Week 24
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.436
	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% -0.2 to 0.4
	Estimation Comments	[Not specified]

7. 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 population with available data

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received 0.5% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (1 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 2 mg/cm²	Participants received 1.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (2 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 4 mg/cm²	Participants received 2.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (4 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Placebo	Participants received placebo administered in 0.2 mL injections, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Measured Values

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Deoxycholic Acid Injection 4 mg/cm²	Placebo
Number of Participants Analyzed	7	11	8	13
Change From Baseline in the Cervicomental Angle [units: degrees] Mean (Standard Deviation)	-0.7 (3.45)	2.3 (13.67)	6.9 (10.67)	-2.3 (9.71)

Statistical Analysis 1 for Change From Baseline in the Cervicomental Angle

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 1 mg/cm², Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.762
	Comments	[Not specified]
	Method	ANCOVA

	Comments	Based on analysis of covariance (ANCOVA) model with treatment as fixed effect and baseline SMF rating as covariate.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	1.6
	Confidence Interval	(2-Sided) 95% -9.1 to 12.3
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Change From Baseline in the Cervicomental Angle

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 2 mg/cm², Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.248
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Based on analysis of covariance (ANCOVA) model with treatment as fixed effect and baseline SMF rating as covariate.

Method of Estimation	Estimation Parameter	Other [LS mean Difference]
	Estimated Value	5.2
	Confidence Interval	(2-Sided) 95% -3.8 to 14.2
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Change From Baseline in the Cervicomental Angle

Statistical Analysis Overview	Comparison Groups	Deoxycholic Acid Injection 4 mg/cm², Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.061
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Based on analysis of covariance (ANCOVA) model with treatment as fixed effect and baseline SMF rating as covariate.

Method of Estimation	Estimation Parameter	Other [LS Mean Difference]
	Estimated Value	9.3
	Confidence Interval	(2-Sided) 95% -0.4 to 19.1
	Estimation Comments	[Not specified]

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 1 mg/cm²	Participants received 0.5% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (1 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 2 mg/cm²	Participants received 1.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (2 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Deoxycholic Acid Injection 4 mg/cm²	Participants received 2.0% deoxycholic acid administered in 0.2 mL injections, up to 4.8 mL (4 mg/cm²) per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Placebo	Participants received placebo administered in 0.2 mL injections, up to 4.8 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Serious Adverse Events

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Deoxycholic Acid Injection 4 mg/cm²	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/20 (0%)	0/20 (0%)	0/22 (0%)	0/22 (0%)

Other Adverse Events

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

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Deoxycholic Acid Injection 4 mg/cm²	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	20/20 (100%)	19/20 (95%)	22/22 (100%)	20/22 (90.91%)
Gastrointestinal disorders				
Abdominal Discomfort [A] †	1/20 (5%)	0/20 (0%)	0/22 (0%)	0/22 (0%)
Diarrhoea [A] †	1/20 (5%)	0/20 (0%)	1/22 (4.55%)	0/22 (0%)
Nausea [A] †	1/20 (5%)	0/20 (0%)	1/22 (4.55%)	0/22 (0%)
General disorders				
Influenza Like Illness [A] †	1/20 (5%)	0/20 (0%)	0/22 (0%)	0/22 (0%)
Injection Site Anaesthesia [A] †	17/20 (85%)	13/20 (65%)	17/22 (77.27%)	4/22 (18.18%)
Injection Site Discomfort [A] †	0/20 (0%)	1/20 (5%)	1/22 (4.55%)	0/22 (0%)
Injection Site Erythema [A] †	3/20 (15%)	5/20 (25%)	6/22 (27.27%)	2/22 (9.09%)
Injection Site Haematoma [A] †	15/20 (75%)	15/20 (75%)	18/22 (81.82%)	12/22 (54.55%)
Injection Site Haemorrhage [A] †	0/20 (0%)	1/20 (5%)	0/22 (0%)	0/22 (0%)
Injection Site Induration [A] †	8/20 (40%)	6/20 (30%)	10/22 (45.45%)	2/22 (9.09%)
Injection Site Nodule [A] †	6/20 (30%)	6/20 (30%)	7/22 (31.82%)	0/22 (0%)
Injection Site Oedema [A] †	2/20 (10%)	1/20 (5%)	0/22 (0%)	1/22 (4.55%)
Injection Site Pain [A] †	19/20 (95%)	16/20 (80%)	19/22 (86.36%)	17/22 (77.27%)
Injection Site Paraesthesia [A] †	1/20 (5%)	1/20 (5%)	2/22 (9.09%)	0/22 (0%)
Injection Site Pruritus [A] †	1/20 (5%)	1/20 (5%)	3/22 (13.64%)	0/22 (0%)
Injection Site Swelling [A] †	17/20 (85%)	17/20 (85%)	19/22 (86.36%)	10/22 (45.45%)
Infections and infestations				

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Deoxycholic Acid Injection 4 mg/cm²	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Bronchitis [A] †	1/20 (5%)	0/20 (0%)	0/22 (0%)	0/22 (0%)
Gastroenteritis [A] †	0/20 (0%)	0/20 (0%)	2/22 (9.09%)	0/22 (0%)
Influenza [A] †	2/20 (10%)	1/20 (5%)	2/22 (9.09%)	0/22 (0%)
Lower Respiratory Tract Infection [A] †	0/20 (0%)	1/20 (5%)	2/22 (9.09%)	0/22 (0%)
Nasopharyngitis [A] †	1/20 (5%)	0/20 (0%)	0/22 (0%)	1/22 (4.55%)
Sinusitis [A] †	1/20 (5%)	0/20 (0%)	0/22 (0%)	0/22 (0%)
Tonsillitis [A] †	2/20 (10%)	0/20 (0%)	0/22 (0%)	0/22 (0%)
Upper Respiratory Tract Infection [A] †	1/20 (5%)	0/20 (0%)	0/22 (0%)	0/22 (0%)
Urinary Tract Infection [A] †	2/20 (10%)	0/20 (0%)	0/22 (0%)	2/22 (9.09%)
Injury, poisoning and procedural complications				
Laceration [A] †	1/20 (5%)	0/20 (0%)	0/22 (0%)	0/22 (0%)
Procedural Pain [A] †	0/20 (0%)	1/20 (5%)	1/22 (4.55%)	0/22 (0%)
Musculoskeletal and connective tissue disorders				
Musculoskeletal Pain [A] †	0/20 (0%)	1/20 (5%)	0/22 (0%)	0/22 (0%)
Neck Pain [A] †	0/20 (0%)	0/20 (0%)	0/22 (0%)	3/22 (13.64%)
Pain In Extremity [A] †	0/20 (0%)	1/20 (5%)	0/22 (0%)	0/22 (0%)
Plantar Fasciitis [A] †	0/20 (0%)	1/20 (5%)	0/22 (0%)	0/22 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Melanocytic Naevus [A] †	0/20 (0%)	1/20 (5%)	0/22 (0%)	0/22 (0%)
Nervous system disorders				
Headache [A] †	1/20 (5%)	3/20 (15%)	4/22 (18.18%)	3/22 (13.64%)
Lethargy [A] †	1/20 (5%)	0/20 (0%)	0/22 (0%)	0/22 (0%)

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Deoxycholic Acid Injection 4 mg/cm²	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Migraine [A] †	1/20 (5%)	1/20 (5%)	0/22 (0%)	1/22 (4.55%)
Monoplegia [A] †	0/20 (0%)	1/20 (5%)	0/22 (0%)	0/22 (0%)
Respiratory, thoracic and mediastinal disorders				
Oropharyngeal Pain [A] †	0/20 (0%)	1/20 (5%)	2/22 (9.09%)	0/22 (0%)
Skin and subcutaneous tissue disorders				
Rosacea [A] †	1/20 (5%)	0/20 (0%)	0/22 (0%)	0/22 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (14.1)

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.

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