Trial record **2 of 2** for: ATX-101-10-17

Previous Study | Return to List | Next Study

Evaluation of Safety and Efficacy of Deoxycholic Acid Injection (ATX-101) in the Reduction of Submental Fat

ClinicalTrials.gov Identifier: NCT01294644

Recruitment Status : Completed
First Posted : February 11, 2011
Results First Posted : June 12, 2015
Last Update Posted : June 12, 2015

Sponsor:
Kythera Biopharmaceuticals

Collaborator:
Bayer

Information provided by (Responsible Party):
Kythera Biopharmaceuticals

Study Details | Tabular View | Study Results | Disclaimer

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double (Participant, Investigator); Primary Purpose: Treatment
Condition:	Moderate or Severe Submental Fullness
Interventions:	Drug: Deoxycholic acid injection Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
The study was conducted at 29 study centers in the European Union.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
The study consisted of a 12-week treatment period and a 12-week safety follow-up period.

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received deoxycholic acid 1 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 deoxycholic acid 2 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 10 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Participant Flow: Overall Study

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Placebo
STARTED	**121**	**122**	**117**
Received Treatment	**118**	**122**	**114**
COMPLETED	**111**	**112**	**103**
NOT COMPLETED	**10**	**10**	**14**
Adverse Event	**2**	**0**	**1**
Withdrawal by Subject	**3**	**7**	**4**
Lost to Follow-up	**3**	**2**	**5**
Miscellaneous Reason	**2**	**1**	**4**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Safety analysis set

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received deoxycholic acid 1 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 deoxycholic acid 2 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 10 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.
Total	Total of all reporting groups

Baseline Measures

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Placebo	Total
Overall Participants Analyzed [Units: Participants]	**118**	**122**	**114**	**354**
Age [Units: Years] Mean (Standard Deviation)	**45.9 (10.21)**	**45.9 (9.95)**	**46.1 (9.50)**	**46.0 (9.87)**
Age, Customized [Units: Participants]				
18 - 50 years	**74**	**80**	**75**	**229**
51 - 65 years	**44**	**42**	**39**	**125**

Gender [Units: Participants]				
Female	**89**	**88**	**78**	**255**
Male	**29**	**34**	**36**	**99**
Race/Ethnicity, Customized [Units: Participants]				
Asian	**1**	**1**	**2**	**4**
Hispanic or Latino	**4**	**7**	**6**	**17**
White	**111**	**114**	**104**	**329**
Other	**2**	**0**	**2**	**4**
Weight [Units: Kg] Mean (Standard Deviation)	**75.69 (10.892)**	**75.60 (10.913)**	**74.62 (11.879)**	**75.32 (11.205)**
Body Mass Index (BMI) [Units: Kg/m²] Mean (Standard Deviation)	**26.26 (2.709)**	**26.53 (2.673)**	**26.06 (2.550)**	**26.29 (2.646)**
Fitzpatrick Skin Type [1] [Units: Participants]				
I-III	**99**	**97**	**91**	**287**
IV-VI	**19**	**25**	**23**	**67**

[1] 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

Hide All Outcome Measures

1. **Primary: Percentage of Participants With a Clinician-Reported Submental Fat Rating Scale (CR-SMFRS) 1-grade Response [Time Frame: Baseline and 12 weeks after last treatment (up to 24 weeks after first dose)]**

Measure Type	Primary
Measure Title	Percentage of Participants With a Clinician-Reported Submental Fat Rating Scale (CR-SMFRS) 1-grade Response
Measure Description	A CR-SMFRS response is defined as at least a 1-point improvement (i.e. 1-point reduction) from Baseline 12 weeks after the last treatment. The CR-SMFRS 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 12 weeks after last treatment (up to 24 weeks after first dose)

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population which included all randomized participants who had at least one efficacy assessment (CR-SMFRS or Subject Self Rating Scale) at Baseline. Last observation carried forward (LOCF) method was used to impute missing data.

Reporting Groups

	Description

Deoxycholic Acid Injection 1 mg/cm²	Participants received deoxycholic acid 1 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 deoxycholic acid 2 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 10 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**	**Placebo**
Participants Analyzed [Units: Participants]	**120**	**122**	**116**
Percentage of Participants With a Clinician-Reported Submental Fat Rating Scale (CR-SMFRS) 1-grade Response [Units: Percentage of participants]	**58.3**	**62.3**	**34.5**

Statistical Analysis 1 for Percentage of Participants With a Clinician-Reported Submental Fat Rating Scale (CR-SMFRS) 1-grade Response

Groups [1]	Deoxycholic Acid Injection 1 mg/cm² vs. Placebo
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Regression, Logistic
P Value [4]	<0.001
Odds Ratio (OR) [5]	2.60
95% Confidence Interval	1.52 to 4.43

[1] Additional details about the analysis, such as null hypothesis and power calculation:

The null hypothesis was there was no difference between deoxycholic acid 1 mg/cm² and placebo.

An adjustment for multiplicity was performed for the two co-primary endpoints. This was accounted for by using the larger of the two P-values in the Bonferroni-Holm scheme.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

Logistic regression analysis with treatment and Baseline CR-SMFRS value in the model.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

[5] Other relevant estimation information:

The odds ratio was based on a logistic regression model adjusted for the Baseline score. Odds ratios >1 indicate a positive treatment effect.

Statistical Analysis 2 for Percentage of Participants With a Clinician-Reported Submental Fat Rating Scale (CR-SMFRS) 1-grade Response

Groups [1]	Deoxycholic Acid Injection 2 mg/cm² vs. Placebo
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Regression, Logistic
P Value [4]	<0.001
Odds Ratio (OR) [5]	3.13
95% Confidence Interval	1.83 to 5.36

[1] Additional details about the analysis, such as null hypothesis and power calculation:

The null hypothesis was there was no difference between deoxycholic acid 2 mg/cm² and placebo.

An adjustment for multiplicity was performed for the two co-primary endpoints. This was accounted for by using the larger of the two P-values in the Bonferroni-Holm scheme.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

Logistic regression analysis with treatment and Baseline CR-SMFRS value in the model.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

[5] Other relevant estimation information:

The odds ratio was based on a logistic regression model adjusted for the Baseline score. Odds ratios >1 indicate a positive treatment effect.

2. Primary: Percentage of Participants With a Subject Self Rating Scale (SSRS) Response [Time Frame: Baseline and 12 weeks after last treatment (up to 24 weeks after first dose)]

Measure Type	Primary
Measure Title	Percentage of Participants With a Subject Self Rating Scale (SSRS) Response
Measure Description	A SSRS response is defined as an SSRS score that is 4 or greater 12 weeks after the last treatment. The SSRS assesses participant's 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.
Time Frame	Baseline and 12 weeks after last treatment (up to 24 weeks after first dose)

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat population; LOCF method was used to impute missing data

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received deoxycholic acid 1 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 deoxycholic acid 2 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 10 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	Placebo
Participants Analyzed [Units: Participants]	**120**	**122**	**116**
Percentage of Participants With a Subject Self Rating Scale (SSRS) Response [Units: Percentage of participants]	**68.3**	**64.8**	**29.3**

Statistical Analysis 1 for Percentage of Participants With a Subject Self Rating Scale (SSRS) Response

Groups [1]	Deoxycholic Acid Injection 1 mg/cm² vs. Placebo
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Regression, Logistic
P Value [4]	<0.001
Odds Ratio (OR) [5]	5.37

95% Confidence Interval	3.06 to 9.44

[1] Additional details about the analysis, such as null hypothesis and power calculation:

The null hypothesis was there was no difference between deoxycholic acid 1 mg/cm² and placebo.

An adjustment for multiplicity was performed for the two co-primary endpoints. This was accounted for by using the larger of the two P-values in the Bonferroni-Holm scheme.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

Logistic regression analysis with treatment and Baseline SSRS value in the model.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

[5] Other relevant estimation information:

Odds ratio was based on a logistic regression model adjusted for Baseline score. Odds ratios >1 indicate a positive treatment effect.

Statistical Analysis 2 for Percentage of Participants With a Subject Self Rating Scale (SSRS) Response

Groups [1]	Deoxycholic Acid Injection 2 mg/cm² vs. Placebo
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Regression, Logistic
P Value [4]	<0.001
Odds Ratio (OR) [5]	4.62
95% Confidence Interval	2.65 to 8.04

[1] Additional details about the analysis, such as null hypothesis and power calculation:

The null hypothesis was there was no difference between deoxycholic acid 2 mg/cm² and placebo.

An adjustment for multiplicity was performed for the two co-primary endpoints. This was accounted for by using the larger of the two P-values in the Bonferroni-Holm scheme.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

Logistic regression analysis with treatment and Baseline SSRS value in the model

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

[5] Other relevant estimation information:

Odds ratio was based on a logistic regression model adjusted for Baseline score. Odds ratios >1 indicate a positive treatment effect.

3. Secondary: Percentage of Participants With a CR-SMFRS 2-grade Response [Time Frame: Baseline and 12 weeks after last treatment (up to 24 weeks after first dose)]

Measure Type	Secondary
Measure Title	Percentage of Participants With a CR-SMFRS 2-grade Response
Measure Description	A CR-SMFRS 2-grade response is defined as at least a 2-point improvement (i.e. 2-point reduction) from Baseline 12 weeks after the last treatment. The CR-SMFRS 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 12 weeks after last treatment (up to 24 weeks after first dose)

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat population; LOCF method was used to impute missing data

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received deoxycholic acid 1 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 deoxycholic acid 2 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 10 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	Placebo
Participants Analyzed [Units: Participants]	**120**	**122**	**116**
Percentage of Participants With a CR-SMFRS 2-grade Response [Units: Percentage of participants]	**9.2**	**9.0**	**0.9**

Statistical Analysis 1 for Percentage of Participants With a CR-SMFRS 2-grade Response

Groups [1]	Deoxycholic Acid Injection 1 mg/cm² vs. Placebo
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Regression, Logistic
P Value [4]	0.020
Odds Ratio (OR) [5]	11.71
95% Confidence Interval	1.48 to 92.67

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

Logistic regression analysis with treatment and Baseline CR-SMFRS value in the model.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

[5] Other relevant estimation information:

Odds ratio was based on a logistic regression model adjusted for the Baseline score. Odds ratios >1 indicate a positive treatment effect.

Statistical Analysis 2 for Percentage of Participants With a CR-SMFRS 2-grade Response

Groups [1]	Deoxycholic Acid Injection 2 mg/cm² vs. Placebo
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Regression, Logistic
P Value [4]	0.021
Odds Ratio (OR) [5]	11.53
95% Confidence Interval	1.46 to 91.24

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

Logistic regression analysis with treatment and Baseline CR-SMFRS value in the model.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

[5] Other relevant estimation information:

Odds ratio was based on a logistic regression model adjusted for the Baseline score. Odds ratios >1 indicate a positive treatment effect.

4. Secondary: Change From Baseline in CR-SMFRS Score [Time Frame: Baseline and 12 weeks after last treatment (up to 24 weeks after first dose)]

Measure Type	Secondary
Measure Title	Change From Baseline in CR-SMFRS Score
Measure Description	The CR-SMFRS 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 12 weeks after last treatment (up to 24 weeks after first dose)

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat population with available data

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received deoxycholic acid 1 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 deoxycholic acid 2 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 10 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	Placebo
Participants Analyzed [Units: Participants]	**111**	**112**	**103**
Change From Baseline in CR-SMFRS Score [Units: Units on a scale] Mean (Standard Deviation)	**-0.7 (0.64)**	**-0.8 (0.61)**	**-0.4 (0.54)**

Statistical Analysis 1 for Change From Baseline in CR-SMFRS Score

Groups [1]	Deoxycholic Acid Injection 1 mg/cm² vs. Placebo
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Mixed Models Repeated Measures
P Value [4]	<0.001
LS Mean Difference [5]	-0.35
95% Confidence Interval	-0.51 to -0.19

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

The model included the fixed effect factors visit and treatment, the visit*treatment interaction, and the Baseline CR-SMFRS values as covariate.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

[5] Other relevant estimation information:

No text entered.

Statistical Analysis 2 for Change From Baseline in CR-SMFRS Score

Groups [1]	Deoxycholic Acid Injection 2 mg/cm² vs. Placebo
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Mixed Models Repeated Measures
P Value [4]	<0.001
LS Mean Difference [5]	-0.40
95% Confidence Interval	-0.56 to -0.24

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

The model included the fixed effect factors visit and treatment, the visit*treatment interaction, and the baseline CR-SMFRS values as covariate.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

[5] Other relevant estimation information:

No text entered.

5. Secondary: Change From Baseline in SSRS Scores [Time Frame: Baseline and 12 weeks after last treatment (up to 24 weeks after first dose)]

Measure Type	Secondary
Measure Title	Change From Baseline in SSRS Scores
Measure Description	The SSRS assesses participant's 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 12 weeks after last treatment (up to 24 weeks after first dose)

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat population with available data

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received deoxycholic acid 1 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 deoxycholic acid 2 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 10 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**	**Placebo**
Participants Analyzed [Units: Participants]	**111**	**111**	**103**
	2.9 (1.61)	**2.9 (1.53)**	**1.5 (1.69)**

Change From Baseline in SSRS Scores [Units: Units on a scale] Mean (Standard Deviation)			

Statistical Analysis 1 for Change From Baseline in SSRS Scores

Groups [1]	Deoxycholic Acid Injection 1 mg/cm² vs. Placebo
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	<0.001
LS Mean Difference [5]	1.36
95% Confidence Interval	0.97 to 1.75

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

The model includes the fixed effect factor treatment and the Baseline values as covariate.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

[5] Other relevant estimation information:

No text entered.

Statistical Analysis 2 for Change From Baseline in SSRS Scores

Groups [1]	Deoxycholic Acid Injection 2 mg/cm² vs. Placebo
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	ANCOVA
P Value [4]	<0.001
LS Mean Difference [5]	1.26

95% Confidence Interval	0.87 to 1.65

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

The model includes the fixed effect factor treatment and the Baseline values as covariate.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

[5] Other relevant estimation information:

No text entered.

6. Secondary: Change From Baseline in Submental Fat Thickness [Time Frame: Baseline and 12 weeks after last treatment (up to 24 weeks after first dose)]

Measure Type	Secondary
Measure Title	Change From Baseline in Submental Fat Thickness
Measure Description	Submental thickness was measured using caliper devices.
Time Frame	Baseline and 12 weeks after last treatment (up to 24 weeks after first dose)

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat population with available data

Reporting Groups

	Description

Deoxycholic Acid Injection 1 mg/cm²	Participants received deoxycholic acid 1 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 deoxycholic acid 2 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 10 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**	**Placebo**
Participants Analyzed [Units: Participants]	**111**	**112**	**102**
Change From Baseline in Submental Fat Thickness [Units: Mm] Mean (Standard Deviation)	**-3.6 (3.67)**	**-3.8 (4.41)**	**-2.5 (3.25)**

Statistical Analysis 1 for Change From Baseline in Submental Fat Thickness

Groups [1]	Deoxycholic Acid Injection 1 mg/cm² vs. Placebo
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Mixed Models Repeated Measures
P Value [4]	0.090
LS Mean Difference [5]	-0.80
95% Confidence Interval	-1.72 to 0.13

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

The model includes the fixed effect factors visit and treatment, the visit*treatment interaction, and the Baseline values as covariate.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

[5] Other relevant estimation information:

No text entered.

Statistical Analysis 2 for Change From Baseline in Submental Fat Thickness

Groups [1]	Deoxycholic Acid Injection 2 mg/cm² vs. Placebo
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Mixed Models Repeated Measures
P Value [4]	0.040
LS Mean Difference [5]	-0.97
95% Confidence Interval	-1.89 to -0.05

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

The model includes the fixed effect factors visit and treatment, the visit*treatment interaction, and the Baseline values as covariate.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

[5] Other relevant estimation information:

No text entered.

7. **Secondary: Change From Baseline in Patient-reported Submental Fat Rating Scale (PR-SMFRS) [Time Frame: Baseline and 12 weeks after last treatment (up to 24 weeks after first dose)]**

Measure Type	Secondary
Measure Title	Change From Baseline in Patient-reported Submental Fat Rating Scale (PR-SMFRS)
Measure Description	The PR-SMFRS is based on the participant's response to the question "How much fat do you currently have under your chin?" answered on a 5-point ordinal scale (0-4) with 0 = no chin fat at all, 1 = a slight amount of chin fat, 2 = a moderate amount of chin fat, 3 = a large amount of chin fat, and 4 = a very large amount of chin fat. Improvement is defined as any decrease in score and worsened as any increase in score.
Time Frame	Baseline and 12 weeks after last treatment (up to 24 weeks after first dose)

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat population with available data

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received deoxycholic acid 1 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 deoxycholic acid 2 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 10 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	Placebo
Participants Analyzed [Units: Participants]	**111**	**110**	**102**
Change From Baseline in Patient-reported Submental Fat Rating Scale (PR-SMFRS) [Units: Percentage of participants]			
Improved	**64.9**	**67.3**	**44.1**
No change	**31.5**	**30.9**	**48.0**
Worsened	**3.6**	**1.8**	**7.8**

Statistical Analysis 1 for Change From Baseline in Patient-reported Submental Fat Rating Scale (PR-SMFRS)

Groups [1]	Deoxycholic Acid Injection 1 mg/cm² vs. Placebo
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Pearson's chi-square test
P Value [4]	0.009

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

Statistical Analysis 2 for Change From Baseline in Patient-reported Submental Fat Rating Scale (PR-SMFRS)

Groups [1]	Deoxycholic Acid Injection 2 mg/cm² vs. Placebo
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Pearson's chi-square test
P Value [4]	0.001

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

8. Secondary: Change From Baseline in Self-rating of Attractiveness [Time Frame: Baseline and 12 weeks after last treatment (up to 24 weeks after first dose)]

Measure Type	Secondary
Measure Title	Change From Baseline in Self-rating of Attractiveness
Measure Description	Self-rating of attractiveness assesses aspects of appearance from the participant's perspective by a series of 6 questions: How attractive do you think your overall appearance (chin/neck, eyes, nose, mouth, entire face) is/are?" Each question was answered on a scale from 1 to 9 where 1 = Not at all attractive, 5 = Neither attractive nor unattractive and 9 = Extremely attractive. A positive change from Baseline indicates improvement.

Time Frame	Baseline and 12 weeks after last treatment (up to 24 weeks after first dose)

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat population with available data

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received deoxycholic acid 1 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 deoxycholic acid 2 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 10 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**	**Placebo**
Participants Analyzed [Units: Participants]	**111**	**110**	**103**
Change From Baseline in Self-rating of Attractiveness [Units: Units on a scale] Mean (Standard Deviation)			
Overall Appearance	**0.6 (1.37)**	**0.6 (1.29)**	**0.3 (1.33)**
Chin / Neck	**1.9 (2.36)**	**2.1 (2.00)**	**0.9 (1.93)**

Eyes	0.3 (1.18)	0.3 (1.55)	0.3 (1.65)
Nose	0.4 (1.53)	0.4 (1.41)	0.5 (1.63)
Mouth	0.1 (1.02)	0.3 (1.25)	0.1 (1.54)
Entire Face	0.4 (1.21)	0.6 (1.12)	0.4 (1.55)

No statistical analysis provided for Change From Baseline in Self-rating of Attractiveness

9. Secondary: Change From Baseline in Patient-Reported Submental Fat Impact Scale (PR-SMFIS) [Time Frame: Baseline and 12 weeks after last treatment (up to 24 weeks after first dose)]

Results not yet reported. Anticipated Reporting Date: 01/2016

10. Secondary: Change From Baseline in Derriford Appearance Scale 24 (DAS24) [Time Frame: Baseline and 12 weeks after last treatment (up to 24 weeks after first dose)]

Results not yet reported. Anticipated Reporting Date: 01/2016

11. Secondary: Change From Baseline in Body Image Quality of Life Inventory (BIQLI) [Time Frame: Baseline and 12 weeks after last treatment (up to 24 weeks after first dose)]

Results not yet reported. Anticipated Reporting Date: 01/2016

Serious Adverse Events

Hide Serious 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	No text entered.

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	

	Participants received deoxycholic acid 1 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 deoxycholic acid 2 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 10 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	Placebo
Total, Serious Adverse Events			
# participants affected / at risk	**1/118 (0.85%)**	**2/122 (1.64%)**	**4/114 (3.51%)**
Gastrointestinal disorders			
Abdominal Pain † [1]			
# participants affected / at risk	**0/118 (0.00%)**	**0/122 (0.00%)**	**1/114 (0.88%)**
General disorders			
Injection Site Nerve Damage † [1]			
# participants affected / at risk	**0/118 (0.00%)**	**1/122 (0.82%)**	**0/114 (0.00%)**
Infections and infestations			
Appendicitis Perforated † [1]			
# participants affected / at risk	**0/118 (0.00%)**	**1/122 (0.82%)**	**0/114 (0.00%)**

Groin Abscess † 1			
# participants affected / at risk	**0/118 (0.00%)**	**0/122 (0.00%)**	**1/114 (0.88%)**
Musculoskeletal and connective tissue disorders			
Osteoarthritis † 1			
# participants affected / at risk	**0/118 (0.00%)**	**0/122 (0.00%)**	**1/114 (0.88%)**
Nervous system disorders			
Syncope † 1			
# participants affected / at risk	**0/118 (0.00%)**	**0/122 (0.00%)**	**1/114 (0.88%)**
Reproductive system and breast disorders			
Endometriosis † 1			
# participants affected / at risk	**1/118 (0.85%)**	**0/122 (0.00%)**	**0/114 (0.00%)**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA v14.1

Other Adverse Events

Hide Other 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	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Deoxycholic Acid Injection 1 mg/cm²	Participants received deoxycholic acid 1 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 deoxycholic acid 2 mg/cm² administered in 0.2 mL injections, up to 10 mL 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 10 mL per treatment session at intervals of approximately 1 month for up to a maximum of 4 treatments.

Other Adverse Events

	Deoxycholic Acid Injection 1 mg/cm²	Deoxycholic Acid Injection 2 mg/cm²	Placebo
Total, Other (not including serious) Adverse Events			
# participants affected / at risk	**116/118 (98.31%)**	**121/122 (99.18%)**	**83/114 (72.81%)**
General disorders			
Injection Site Pain † [1]			
# participants affected / at risk	**104/118 (88.14%)**	**107/122 (87.70%)**	**34/114 (29.82%)**
Injection Site Haematoma † [1]			
# participants affected / at risk	**66/118 (55.93%)**	**60/122 (49.18%)**	**52/114 (45.61%)**
Injection Site Anaesthesia † [1]			
# participants affected / at risk	**52/118 (44.07%)**	**64/122 (52.46%)**	**1/114 (0.88%)**
Injection Site Swelling † [1]			

# participants affected / at risk	55/118 (46.61%)	55/122 (45.08%)	20/114 (17.54%)
Injection Site Erythema † 1			
# participants affected / at risk	50/118 (42.37%)	52/122 (42.62%)	25/114 (21.93%)
Injection Site Induration † 1			
# participants affected / at risk	16/118 (13.56%)	24/122 (19.67%)	1/114 (0.88%)
Injection Site Haemorrhage † 1			
# participants affected / at risk	15/118 (12.71%)	17/122 (13.93%)	12/114 (10.53%)
Injection Site Oedema † 1			
# participants affected / at risk	13/118 (11.02%)	17/122 (13.93%)	5/114 (4.39%)
Injection Site Pruritus † 1			
# participants affected / at risk	11/118 (9.32%)	9/122 (7.38%)	2/114 (1.75%)
Injection Site Paraesthesia † 1			
# participants affected / at risk	9/118 (7.63%)	10/122 (8.20%)	0/114 (0.00%)
Injection Site Hypersensitivity † 1			
# participants affected / at risk	7/118 (5.93%)	10/122 (8.20%)	2/114 (1.75%)
Infections and infestations			
Nasopharyngitis † 1			
# participants affected / at risk	13/118 (11.02%)	8/122 (6.56%)	6/114 (5.26%)
Nervous system disorders			

Headache † 1			
# participants affected / at risk	**17/118 (14.41%)**	**8/122 (6.56%)**	**16/114 (14.04%)**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA v14.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

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

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

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: 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:

Name/Title: Clinical Trial Disclosure
Organization: Kythera
e-mail: clinical_trials@kythera.com

Responsible Party:	Kythera Biopharmaceuticals
ClinicalTrials.gov Identifier:	NCT01294644 History of Changes
Other Study ID Numbers:	**ATX-101-10-17** 2010-020691-28 (EudraCT Number)
First Submitted:	February 10, 2011
First Posted:	February 11, 2011
Results First Submitted:	May 28, 2015
Results First Posted:	June 12, 2015
Last Update Posted:	June 12, 2015