



Clinical trial results:

A Randomised, Double-blind, Placebo-Controlled, Phase II Study to Assess the Efficacy and Safety of Topically Applied DGLA Cream in Patients with Mild to Moderate Acne Vulgaris

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2012-004965-41 |
| Trial protocol | DE HU SK |
| Global end of trial date | 10 February 2014 |

Results information

| | |
|--------------------------------|-------------|
| Result version number | v1 |
| This version publication date | 25 May 2022 |
| First version publication date | 25 May 2022 |

Trial information

Trial identification

| | |
|-----------------------|-----------|
| Sponsor protocol code | DS107E-03 |
|-----------------------|-----------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Dignity Sciences Limited |
| Sponsor organisation address | Trintech Building, South County Business Park, Dublin 18, Ireland, Dublin 18 |
| Public contact | David Coughlan, Dignity Sciences Limited, +353 12933590, david.coughlan@dignitysciences.com |
| Scientific contact | David Coughlan, Dignity Sciences Limited, +353 12933590, david.coughlan@dignitysciences.com |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 27 June 2014 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 16 January 2014 |
| Global end of trial reached? | Yes |
| Global end of trial date | 10 February 2014 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this proof-of-concept study was to compare the efficacy of different concentrations of the study treatment (DS107E, dihomogamma-linolenic acid [DGLA] cream) on facial papulopustular acne in comparison to a placebo control. The secondary objective of this study was to assess the safety and tolerability of topically applied DS107E DGLA cream in different concentrations.

Protection of trial subjects:

The study was managed and conducted according to the latest International Conference on Harmonisation (ICH) guidelines for Good Clinical Practice (GCP) and applicable regulatory requirement(s) (specifically the principles of GCP in ICH topic E6, as laid down by the Commission Directive 2005/28/EC and in accordance with applicable local laws and guidelines).

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 10 June 2013 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------|
| Country: Number of subjects enrolled | Slovakia: 56 |
| Country: Number of subjects enrolled | Germany: 34 |
| Country: Number of subjects enrolled | Hungary: 64 |
| Worldwide total number of subjects | 154 |
| EEA total number of subjects | 154 |

Notes:

Subjects enrolled per age group

| | |
|---|-----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 32 |
| Adults (18-64 years) | 122 |

| | |
|---------------------|---|
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Study was carried out in 3 countries (Germany, Slovakia, and Hungary) across 16 investigational sites.

Pre-assignment

Screening details:

The study consisted of a wash out period of maximum 14 days; a 12-week treatment period and a 4 week follow up period.

Period 1

| | |
|------------------------------|---------------------------------------|
| Period 1 title | Overall Study Period (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator |

Arms

| | |
|------------------------------|----------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | DS107E Placebo cream |

Arm description:

DS107E Placebo Cream applied topically to all affected areas twice-daily for 12 weeks. The DS107E Placebo Cream was identical in composition to formulation of DS107E DGLA cream minus active drug substance.

| | |
|--|------------------------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo matching DS107E DGLA Cream |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical |

Dosage and administration details:

DS107E Placebo Cream applied topically to all affected areas twice-daily for 12 weeks.

| | |
|------------------|----------------------|
| Arm title | DS107E DGLA 1% cream |
|------------------|----------------------|

Arm description:

DS107E DGLA 1% Cream applied topically to all affected areas twice-daily for 12 weeks.

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | DS107E DGLA Cream |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical |

Dosage and administration details:

DS107E DGLA 1% Cream applied topically to all affected areas twice-daily for 12 weeks.

| | |
|------------------|----------------------|
| Arm title | DS107E DGLA 5% cream |
|------------------|----------------------|

Arm description:

DS107E DGLA 5% Cream applied topically to all affected areas twice-daily for 12 weeks

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|----------------------|
| Investigational medicinal product name | DS107E DGLA 5% cream |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical |

Dosage and administration details:

DS107E DGLA 5% Cream applied topically to all affected areas twice-daily for 12 weeks.

| Number of subjects in period 1 | DS107E Placebo cream | DS107E DGLA 1% cream | DS107E DGLA 5% cream |
|---------------------------------------|----------------------|----------------------|----------------------|
| Started | 49 | 53 | 52 |
| Completed | 46 | 49 | 44 |
| Not completed | 3 | 4 | 8 |
| Adverse event, non-fatal | 1 | - | - |
| Other | - | 1 | 1 |
| Subject request | - | 1 | 4 |
| Lost to follow-up | - | 2 | - |
| Lack of efficacy | 2 | - | 1 |
| Protocol deviation | - | - | 2 |

Baseline characteristics

Reporting groups

| | |
|---|----------------------|
| Reporting group title | DS107E Placebo cream |
| Reporting group description: DS107E Placebo Cream applied topically to all affected areas twice-daily for 12 weeks. The DS107E Placebo Cream was identical in composition to formulation of DS107E DGLA cream minus active drug substance. | |
| Reporting group title | DS107E DGLA 1% cream |
| Reporting group description: DS107E DGLA 1% Cream applied topically to all affected areas twice-daily for 12 weeks. | |
| Reporting group title | DS107E DGLA 5% cream |
| Reporting group description: DS107E DGLA 5% Cream applied topically to all affected areas twice-daily for 12 weeks | |

| Reporting group values | DS107E Placebo cream | DS107E DGLA 1% cream | DS107E DGLA 5% cream |
|--|----------------------|----------------------|----------------------|
| Number of subjects | 49 | 53 | 52 |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 14 | 7 | 11 |
| Adults (18-64 years) | 35 | 46 | 41 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Age continuous Units: years | | | |
| arithmetic mean | 22.7 | 23.1 | 22.8 |
| standard deviation | ± 6.33 | ± 6.06 | ± 5.78 |
| Gender categorical Units: Subjects | | | |
| Female | 35 | 45 | 34 |
| Male | 14 | 8 | 18 |
| Race Units: Subjects | | | |
| White | 48 | 52 | 50 |
| Black | 0 | 1 | 0 |
| Asian | 0 | 0 | 0 |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Native Hawaiian or other Pacific Islander | 0 | 0 | 0 |
| Other | 0 | 0 | 1 |
| Mixed | 1 | 0 | 1 |
| Missing | 0 | 0 | 0 |

| Reporting group values | Total | | |
|---|-------|--|--|
| Number of subjects | 154 | | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | | |
| Newborns (0-27 days) | 0 | | |
| Infants and toddlers (28 days-23 months) | 0 | | |
| Children (2-11 years) | 0 | | |
| Adolescents (12-17 years) | 32 | | |
| Adults (18-64 years) | 122 | | |
| From 65-84 years | 0 | | |
| 85 years and over | 0 | | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | | | |
| standard deviation | - | | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 114 | | |
| Male | 40 | | |
| Race | | | |
| Units: Subjects | | | |
| White | 150 | | |
| Black | 1 | | |
| Asian | 0 | | |
| American Indian or Alaska Native | 0 | | |
| Native Hawaiian or other Pacific Islander | 0 | | |
| Other | 1 | | |
| Mixed | 2 | | |
| Missing | 0 | | |

End points

End points reporting groups

| | |
|---|----------------------|
| Reporting group title | DS107E Placebo cream |
| Reporting group description: DS107E Placebo Cream applied topically to all affected areas twice-daily for 12 weeks. The DS107E Placebo Cream was identical in composition to formulation of DS107E DGLA cream minus active drug substance. | |
| Reporting group title | DS107E DGLA 1% cream |
| Reporting group description: DS107E DGLA 1% Cream applied topically to all affected areas twice-daily for 12 weeks. | |
| Reporting group title | DS107E DGLA 5% cream |
| Reporting group description: DS107E DGLA 5% Cream applied topically to all affected areas twice-daily for 12 weeks | |

Primary: Change in Investigators Global Assessment (IGA) of acne severity from baseline to the end of week 12.

| | |
|--|---|
| End point title | Change in Investigators Global Assessment (IGA) of acne severity from baseline to the end of week 12. |
| End point description: Mean Change from Baseline of IGA Score to Week 12. | |
| End point type | Primary |
| End point timeframe: Up to 12 weeks. | |

| End point values | DS107E Placebo cream | DS107E DGLA 1% cream | DS107E DGLA 5% cream | |
|--------------------------------------|----------------------|----------------------|----------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 46 | 50 | 44 | |
| Units: IGA scores | | | | |
| arithmetic mean (standard deviation) | -0.4 (± 0.75) | -0.3 (± 0.64) | -0.3 (± 0.56) | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | DS107E DGLA 1% Cream V Placebo |
| Comparison groups | DS107E Placebo cream v DS107E DGLA 1% cream |
| Number of subjects included in analysis | 96 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.74 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -0.1 |
| upper limit | 0.3 |

| | |
|---|---|
| Statistical analysis title | DS107E DGLA 5% Cream V Placebo |
| Comparison groups | DS107E Placebo cream v DS107E DGLA 5% cream |
| Number of subjects included in analysis | 90 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.909 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0.4 |

| | |
|---|---|
| Primary: Change of total count of acne lesions from baseline to the end of week 12 | |
| End point title | Change of total count of acne lesions from baseline to the end of week 12 |
| End point description: Mean Change from Baseline of Total Lesion Count to Week 12. | |
| End point type | Primary |
| End point timeframe: Up to 12 weeks. | |

| End point values | DS107E Placebo cream | DS107E DGLA 1% cream | DS107E DGLA 5% cream | |
|--------------------------------------|-------------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 46 | 50 | 44 | |
| Units: Total lesion count | | | | |
| arithmetic mean (standard deviation) | -32.5 (± 29.42) | -30.5 (± 32.03) | -27.1 (± 25.68) | |

Statistical analyses

| | |
|-----------------------------------|---|
| Statistical analysis title | DS107E DGLA 1% Cream V Placebo |
| Comparison groups | DS107E Placebo cream v DS107E DGLA 1% cream |

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 96 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.651 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -6.9 |
| upper limit | 11.2 |

| | |
|---|---|
| Statistical analysis title | DS107E DGLA 5% Cream V Placebo |
| Comparison groups | DS107E Placebo cream v DS107E DGLA 5% cream |
| Number of subjects included in analysis | 90 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.876 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Confidence interval | |
| level | 90 % |
| sides | 2-sided |
| lower limit | -2.8 |
| upper limit | 15.9 |

Secondary: Change in Investigators Global Assessment (IGA) of acne severity after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment).

| | |
|-----------------|---|
| End point title | Change in Investigators Global Assessment (IGA) of acne severity after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment). |
|-----------------|---|

End point description:

| | |
|----------------------|-----------------|
| End point type | Secondary |
| End point timeframe: | Up to 16 weeks. |

| End point values | DS107E Placebo cream | DS107E DGLA 1% cream | DS107E DGLA 5% cream | |
|--------------------------------------|----------------------|----------------------|----------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 53 | 51 | |
| Units: IGA Scores | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 | -0.1 (± 0.47) | -0.1 (± 0.43) | -0.1 (± 0.38) | |

| | | | | |
|---------|---------------|---------------|---------------|--|
| Week 4 | -0.1 (± 0.47) | -0.1 (± 0.39) | -0.2 (± 0.43) | |
| Week 8 | -0.4 (± 0.69) | -0.3 (± 0.55) | -0.3 (± 0.52) | |
| Week 12 | -0.4 (± 0.75) | -0.3 (± 0.64) | -0.3 (± 0.56) | |
| Week 16 | -0.3 (± 0.84) | -0.4 (± 0.79) | -0.4 (± 0.66) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Total Lesion Count).

| | |
|---|--|
| End point title | Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Total Lesion Count). |
| End point description: | |
| Mean Change from Baseline of Total Lesion Count by Visit. | |
| End point type | Secondary |
| End point timeframe: | |
| Up to 16 weeks | |

| End point values | DS107E Placebo cream | DS107E DGLA 1% cream | DS107E DGLA 5% cream | |
|--------------------------------------|-------------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 53 | 51 | |
| Units: Total lesion count | | | | |
| arithmetic mean (standard deviation) | | | | |
| Change from Baseline to Week 2 | -12.4 (± 16.27) | -14.8 (± 17.32) | -10.6 (± 19.09) | |
| Observed value Week 2 | 67.4 (± 46.41) | 59.6 (± 34.06) | 68.8 (± 37.95) | |
| Change from Baseline to Week 4 | -22.4 (± 19.08) | -23.0 (± 19.58) | -17.0 (± 21.80) | |
| Observed value Week 4 | 52.6 (± 30.01) | 51.4 (± 34.42) | 60.8 (± 36.55) | |
| Change from Baseline to Week 8 | -30.7 (± 28.81) | -26.5 (± 29.07) | -20.5 (± 42.98) | |
| Observed value Week 8 | 43.2 (± 29.97) | 47.5 (± 40.8) | 56.3 (± 42.98) | |
| Change from Baseline to Week 12 | -32.5 (± 29.42) | -30.5 (± 32.03) | -27.1 (± 25.68) | |
| Observed value Week 12 | 41.5 (± 34.27) | 43.8 (± 39.01) | 50.4 (± 34.29) | |
| Change from Baseline to Week 16 | -28.5 (± 30.99) | -34.3 (± 40.55) | -24.8 (± 35.53) | |
| Observed value Week 16 | 51.3 (± 48.17) | 40.8 (± 32.00) | 54.6 (± 41.63) | |

Statistical analyses

Secondary: Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Inflammatory Lesion Count).

| | |
|------------------------|---|
| End point title | Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Inflammatory Lesion Count). |
| End point description: | Mean change from baseline of Inflammatory Lesion Count by Visit. |
| End point type | Secondary |
| End point timeframe: | Up to 16 weeks. |

| End point values | DS107E Placebo cream | DS107E DGLA 1% cream | DS107E DGLA 5% cream | |
|--------------------------------------|-------------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 53 | 51 | |
| Units: Total count | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 | -6.3 (± 8.38) | -7.0 (± 12.85) | -5.4 (± 10.00) | |
| Week 4 | -12.4 (± 10.62) | -12.0 (± 12.04) | -10.4 (± 12.75) | |
| Week 8 | -14.4 (± 12.44) | -13.6 (± 12.14) | -12.8 (± 14.46) | |
| Week 12 | -15.5 (± 12.67) | -15.1 (± 13.48) | -14.6 (± 12.92) | |
| Week 16 | -13.8 (± 13.56) | -15.9 (± 15.31) | -12.4 (± 19.06) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Non-inflammatory Lesion Count).

| | |
|------------------------|---|
| End point title | Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Non-inflammatory Lesion Count). |
| End point description: | Mean change from baseline of Non-inflammatory Lesion Count by Visit. |
| End point type | Secondary |
| End point timeframe: | Up to 16 weeks. |

| End point values | DS107E Placebo cream | DS107E DGLA 1% cream | DS107E DGLA 5% cream | |
|--------------------------------------|-------------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 53 | 51 | |
| Units: Total count | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 | -6.1 (± 11.45) | -7.8 (± 16.45) | -5.1 (± 16.55) | |
| Week 4 | -9.9 (± 11.73) | -10.9 (± 21.13) | -6.5 (± 18.34) | |
| Week 8 | -16.2 (± 20.46) | -12.9 (± 26.40) | -7.6 (± 20.83) | |
| Week 12 | -17.0 (± 22.72) | -15.4 (± 30.84) | -12.4 (± 19.16) | |
| Week 16 | -14.9 (± 23.45) | -18.4 (± 38.74) | -12.4 (± 23.13) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Inflammatory and Non-inflammatory)

| | |
|------------------------|--|
| End point title | Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Inflammatory and Non-inflammatory) |
| End point description: | Mean change from baseline of Inflammatory and Non-inflammatory Lesion Count by Visit. |
| End point type | Secondary |
| End point timeframe: | Up to 16 weeks. |

| End point values | DS107E Placebo cream | DS107E DGLA 1% cream | DS107E DGLA 5% cream | |
|--------------------------------------|-------------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 53 | 51 | |
| Units: Total count | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 | -12.4 (± 16.18) | -14.8 (± 17.34) | -10.5 (± 19.16) | |
| Week 4 | -22.3 (± 19.17) | -22.9 (± 19.55) | -16.9 (± 21.85) | |
| Week 8 | -30.6 (± 28.71) | -26.5 (± 28.98) | -20.4 (± 28.25) | |

| | | | | |
|---------|--------------------|--------------------|--------------------|--|
| Week 12 | -32.5 (± 29.22) | -30.5 (± 31.84) | -27.0 (± 25.61) | |
| Week 16 | -28.8 (± 30.63) | -34.3 (± 40.47) | -24.7 (± 35.33) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Total lesion count).

| | |
|------------------------|--|
| End point title | Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Total lesion count). |
| End point description: | Mean Percent Change from Baseline of Total Lesion Count by Visit. |
| End point type | Secondary |
| End point timeframe: | Up to 16 weeks. |

| End point values | DS107E Placebo cream | DS107E DGLA 1% cream | DS107E DGLA 5% cream | |
|--------------------------------------|-------------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 53 | 51 | |
| Units: Total lesion count | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 | -16.9 (± 19.53) | -19.0 (± 21.19) | -14.1 (± 21.82) | |
| Week 4 | -29.3 (± 24.52) | -31.8 (± 22.87) | -21.4 (± 25.72) | |
| Week 8 | -41.4 (± 28.84) | -37.2 (± 33.55) | -26.4 (± 36.94) | |
| Week 12 | -45.8 (± 27.37) | -40.0 (± 45.74) | -33.3 (± 36.02) | |
| Week 16 | -37.3 (± 30.30) | -37.9 (± 63.23) | -30.0 (± 39.28) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Inflammatory lesion count).

| | |
|--|---|
| End point title | Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Inflammatory lesion count). |
| End point description: Mean Percent Change from Baseline of Inflammatory Lesion Count by Visit. | |
| End point type | Secondary |
| End point timeframe: Up to 16 weeks. | |

| End point values | DS107E Placebo cream | DS107E DGLA 1% cream | DS107E DGLA 5% cream | |
|--------------------------------------|-------------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 53 | 51 | |
| Units: Total count | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 | -23.2 (± 32.41) | -12.3 (± 73.59) | -18.3 (± 27.01) | |
| Week 4 | -41.7 (± 30.56) | -33.9 (± 54.63) | -32.3 (± 34.59) | |
| Week 8 | -50.1 (± 36.89) | -43.6 (± 40.37) | -42.4 (± 38.84) | |
| Week 12 | -53.3 (± 37.14) | -46.5 (± 73.84) | -47.6 (± 32.10) | |
| Week 16 | -48.5 (± 39.47) | -52.4 (± 47.30) | -40.6 (± 42.96) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Non-inflammatory lesion count).

| | |
|--|---|
| End point title | Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Non-inflammatory lesion count). |
| End point description: Mean Percent Change from Baseline of Non-inflammatory Lesion Count by Visit. | |
| End point type | Secondary |
| End point timeframe: Up to 16 weeks. | |

| End point values | DS107E Placebo cream | DS107E DGLA 1% cream | DS107E DGLA 5% cream | |
|--------------------------------------|-------------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 53 | 51 | |
| Units: Total count | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 | -4.4 (± 64.80) | -4.2 (± 82.82) | -1.7 (± 61.51) | |
| Week 4 | -19.6 (± 36.05) | -13.3 (± 81.70) | 36.9 (± 365.18) | |
| Week 8 | -33.9 (± 33.64) | -14.9 (± 93.07) | 27.2 (± 280.62) | |
| Week 12 | -40.9 (± 32.07) | -11.7 (± 113.97) | 10.9 (± 236.25) | |
| Week 16 | -23.6 (± 54.52) | 0.2 (± 157.74) | 11.8 (± 225.53) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Inflammatory and Non-inflammatory).

| | |
|-----------------|---|
| End point title | Count of acne lesions in the face after 2, 4, 8 and 12 weeks of treatment and at follow-up (4 weeks after the end of treatment) and its percentage and absolute change to baseline for the three parameters separately (Inflammatory and Non-inflammatory). |
|-----------------|---|

End point description:

Mean Percent Change from Baseline of Inflammatory and Non-inflammatory Lesion Count by Visit.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to 16 weeks.

| End point values | DS107E Placebo cream | DS107E DGLA 1% cream | DS107E DGLA 5% cream | |
|--------------------------------------|-------------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 53 | 51 | |
| Units: Total count | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 | -17.1 (± 19.76) | -19.1 (± 21.26) | -14.1 (± 21.92) | |
| Week 4 | -29.2 (± 24.70) | -31.8 (± 22.86) | -21.4 (± 25.73) | |
| Week 8 | -41.4 (± 29.00) | -37.2 (± 33.43) | -26.4 (± 36.93) | |
| Week 12 | -45.9 (± 27.17) | -40.00 (± 45.60) | -33.3 (± 36.01) | |
| Week 16 | -37.7 (± 30.07) | -38.0 (± 63.14) | -30.0 (± 39.17) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Reduction of acne lesions by >30%

| | |
|-----------------|---|
| End point title | Time to Reduction of acne lesions by >30% |
|-----------------|---|

End point description:

Analysis of Time to Reduction of Total Lesion Count by >30% from Baseline.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to 16 weeks

| End point values | DS107E Placebo cream | DS107E DGLA 1% cream | DS107E DGLA 5% cream | |
|-----------------------------|-------------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 49 | 53 | 51 | |
| Units: Events observed | | | | |
| Event observed | 40 | 42 | 34 | |
| Censored | 9 | 11 | 17 | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 16 weeks.

Adverse event reporting additional description:

Any undesirable experience occurring to a patient that has signed the ICF, whether or not considered related to the investigational treatment. All Adverse Events must be recorded in the case report form, defining relationship to treatment and severity.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 16.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|----------------------|
| Reporting group title | DS107E Placebo cream |
|-----------------------|----------------------|

Reporting group description:

DS107E Placebo Cream applied topically to all affected areas twice-daily for 12 weeks. The DS107E Placebo Cream was identical in composition to formulation of DS107E DGLA cream minus active drug substance.

| | |
|-----------------------|----------------------|
| Reporting group title | DS107E DGLA 1% cream |
|-----------------------|----------------------|

Reporting group description:

DS107E DGLA 1% Cream applied topically to all affected areas twice-daily for 12 weeks.

| | |
|-----------------------|----------------------|
| Reporting group title | DS107E DGLA 5% cream |
|-----------------------|----------------------|

Reporting group description:

DS107E DGLA 5% Cream applied topically to all affected areas twice-daily for 12 weeks

| Serious adverse events | DS107E Placebo cream | DS107E DGLA 1% cream | DS107E DGLA 5% cream |
|---|----------------------|----------------------|----------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 1 / 53 (1.89%) | 0 / 52 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Infections and infestations | | | |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 1 / 53 (1.89%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

| Non-serious adverse events | DS107E Placebo cream | DS107E DGLA 1% cream | DS107E DGLA 5% cream |
|---|----------------------|----------------------|----------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 21 / 49 (42.86%) | 18 / 53 (33.96%) | 21 / 52 (40.38%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Melanocytic naevus | | | |
| subjects affected / exposed | 1 / 49 (2.04%) | 1 / 53 (1.89%) | 0 / 52 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| General disorders and administration site conditions | | | |
| Application site pain | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 1 / 53 (1.89%) | 2 / 52 (3.85%) |
| occurrences (all) | 0 | 1 | 2 |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 49 (2.04%) | 0 / 53 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 1 | 0 | 1 |
| Oedema | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 1 / 53 (1.89%) | 0 / 52 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 53 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 0 | 0 | 1 |
| Immune system disorders | | | |
| Allergy to animal | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 1 / 53 (1.89%) | 0 / 52 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 3 / 49 (6.12%) | 1 / 53 (1.89%) | 0 / 52 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Menstrual discomfort | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 1 / 53 (1.89%) | 0 / 52 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Premenstrual pain | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 53 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 0 | 0 | 1 |
| Premenstrual syndrome | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 49 (0.00%) 0 | 0 / 53 (0.00%) 0 | 1 / 52 (1.92%) 1 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 1 / 49 (2.04%) | 1 / 53 (1.89%) | 0 / 52 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 1 / 53 (1.89%) | 1 / 52 (1.92%) |
| occurrences (all) | 0 | 1 | 1 |
| Nasal congestion | | | |
| subjects affected / exposed | 1 / 49 (2.04%) | 0 / 53 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 1 / 49 (2.04%) | 0 / 53 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rhinitis allergic | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 53 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 0 | 0 | 1 |
| Psychiatric disorders | | | |
| Depression | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 53 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 0 | 0 | 1 |
| Panic attack | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 1 / 53 (1.89%) | 0 / 52 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Investigations | | | |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 2 / 49 (4.08%) | 0 / 53 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 53 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 0 | 0 | 1 |
| Body temperature increased | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 53 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 0 | 0 | 1 |
| Lymph node palpable | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 1 / 49 (2.04%) 1 | 0 / 53 (0.00%) 0 | 0 / 52 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |
| Arthropod sting | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 1 / 53 (1.89%) | 1 / 52 (1.92%) |
| occurrences (all) | 0 | 1 | 1 |
| Hand fracture | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 53 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 0 | 0 | 1 |
| Road traffic accident | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 1 / 53 (1.89%) | 0 / 52 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 5 / 49 (10.20%) | 1 / 53 (1.89%) | 4 / 52 (7.69%) |
| occurrences (all) | 6 | 2 | 9 |
| Migraine | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 53 (0.00%) | 2 / 52 (3.85%) |
| occurrences (all) | 0 | 0 | 4 |
| Gastrointestinal disorders | | | |
| Toothache | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 1 / 53 (1.89%) | 3 / 52 (5.77%) |
| occurrences (all) | 0 | 1 | 3 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 53 (0.00%) | 2 / 52 (3.85%) |
| occurrences (all) | 0 | 0 | 6 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 49 (2.04%) | 0 / 53 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 53 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 2 / 49 (4.08%) | 0 / 53 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |

| | | | |
|--|---------------------|---------------------|---------------------|
| Dermatitis allergic subjects affected / exposed occurrences (all) | 0 / 49 (0.00%) 0 | 1 / 53 (1.89%) 1 | 1 / 52 (1.92%) 1 |
| Alopecia subjects affected / exposed occurrences (all) | 0 / 49 (0.00%) 0 | 1 / 53 (1.89%) 1 | 0 / 52 (0.00%) 0 |
| Angiokeratoma subjects affected / exposed occurrences (all) | 0 / 49 (0.00%) 0 | 1 / 53 (1.89%) 1 | 0 / 52 (0.00%) 0 |
| Skin exfoliation subjects affected / exposed occurrences (all) | 1 / 49 (2.04%) 1 | 0 / 53 (0.00%) 0 | 0 / 52 (0.00%) 0 |
| Renal and urinary disorders Nephrolithiasis subjects affected / exposed occurrences (all) | 1 / 49 (2.04%) 1 | 0 / 53 (0.00%) 0 | 0 / 52 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all) | 0 / 49 (0.00%) 0 | 1 / 53 (1.89%) 1 | 1 / 52 (1.92%) 1 |
| Arthralgia subjects affected / exposed occurrences (all) | 0 / 49 (0.00%) 0 | 1 / 53 (1.89%) 1 | 0 / 52 (0.00%) 0 |
| Intervertebral disc disorder subjects affected / exposed occurrences (all) | 0 / 49 (0.00%) 0 | 0 / 53 (0.00%) 0 | 1 / 52 (1.92%) 1 |
| Muscle tightness subjects affected / exposed occurrences (all) | 0 / 49 (0.00%) 0 | 0 / 53 (0.00%) 0 | 1 / 52 (1.92%) 1 |
| Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) | 4 / 49 (8.16%) 4 | 3 / 53 (5.66%) 4 | 2 / 52 (3.85%) 2 |
| Influenza subjects affected / exposed occurrences (all) | 0 / 49 (0.00%) 0 | 2 / 53 (3.77%) 2 | 2 / 52 (3.85%) 2 |

| | | | |
|-----------------------------------|----------------|----------------|----------------|
| Pharyngitis | | | |
| subjects affected / exposed | 1 / 49 (2.04%) | 2 / 53 (3.77%) | 1 / 52 (1.92%) |
| occurrences (all) | 1 | 2 | 1 |
| Gastroenteritis | | | |
| subjects affected / exposed | 2 / 49 (4.08%) | 0 / 53 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 1 / 53 (1.89%) | 1 / 52 (1.92%) |
| occurrences (all) | 0 | 1 | 1 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 53 (0.00%) | 2 / 52 (3.85%) |
| occurrences (all) | 0 | 0 | 2 |
| Viral infection | | | |
| subjects affected / exposed | 1 / 49 (2.04%) | 0 / 53 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 1 | 0 | 1 |
| Abscess | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 53 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 0 | 0 | 1 |
| Acute sinusitis | | | |
| subjects affected / exposed | 1 / 49 (2.04%) | 0 / 53 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 1 / 53 (1.89%) | 0 / 52 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 53 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 0 | 0 | 1 |
| Laryngitis | | | |
| subjects affected / exposed | 1 / 49 (2.04%) | 0 / 53 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 1 / 49 (2.04%) | 0 / 53 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 49 (0.00%) | 0 / 53 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|---------------------|---------------------|---------------------|
| Postoperative wound infection subjects affected / exposed occurrences (all) | 0 / 49 (0.00%) 0 | 1 / 53 (1.89%) 1 | 0 / 52 (0.00%) 0 |
| Rhinitis subjects affected / exposed occurrences (all) | 0 / 49 (0.00%) 0 | 0 / 53 (0.00%) 0 | 1 / 52 (1.92%) 1 |
| Tooth infection subjects affected / exposed occurrences (all) | 0 / 49 (0.00%) 0 | 0 / 53 (0.00%) 0 | 1 / 52 (1.92%) 1 |
| Urinary tract infection subjects affected / exposed occurrences (all) | 0 / 49 (0.00%) 0 | 1 / 53 (1.89%) 1 | 0 / 52 (0.00%) 0 |
| Metabolism and nutrition disorders Hypertriglyceridaemia subjects affected / exposed occurrences (all) | 1 / 49 (2.04%) 1 | 0 / 53 (0.00%) 0 | 0 / 52 (0.00%) 0 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------|--|
| 22 May 2013 | CRO name removed update to inclusion and exclusion criteria. Washout phase clarification Application of IMP clarification Baseline visit window clarification Concomitant medication clarification |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported