



Clinical trial results:

Benzaknen® 5% Gel in combination with Dermotivin® Soft Liquid cleanser and non-comedogenic Cetaphil® Dermacontrol Moisturizer SPF30 in the treatment of mild-to-moderate acne vulgaris

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2015-001448-13 |
| Trial protocol | DE |
| Global end of trial date | 15 January 2016 |

Results information

| | |
|--------------------------------|-------------|
| Result version number | v1 |
| This version publication date | 13 May 2017 |
| First version publication date | 13 May 2017 |

Trial information

Trial identification

| | |
|-----------------------|------------------|
| Sponsor protocol code | RD.03.SPR.105041 |
|-----------------------|------------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02589405 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Galderma R&D |
| Sponsor organisation address | 240 routes des colles, BIOT, France, 06410 |
| Public contact | Stéphanie Leclerc, Galderma R&D, +33 492386706, Stephanie.Leclerc@galderma.com |
| Scientific contact | Stéphanie Leclerc, Galderma R&D, +33 492386706, Stephanie.Leclerc@galderma.com |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|-----------------|
| Analysis stage | Final |
| Date of interim/final analysis | 04 March 2016 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 15 January 2016 |
| Global end of trial reached? | Yes |
| Global end of trial date | 15 January 2016 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study is to evaluate subject satisfaction with the treatment regimen comprising Benzaknen® 5% Gel in association with Dermotivin® Soft Liquid cleanser and Cetaphil® Dermacontrol Moisturizer SPF30 after 12 weeks of treatment.

Protection of trial subjects:

All study participants were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

| | |
|---|----------------|
| Actual start date of recruitment | 26 August 2015 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects**Subjects enrolled per country**

| | |
|--------------------------------------|-------------|
| Country: Number of subjects enrolled | Germany: 50 |
| Worldwide total number of subjects | 50 |
| EEA total number of subjects | 50 |

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) | 21 |
| Adults (18-64 years) | 29 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

No screening

Period 1

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

Arms

| | |
|------------------|-------------------|
| Arm title | Treatment regimen |
|------------------|-------------------|

Arm description: -

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Benzaknen® 5% Gel |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Gel |
| Routes of administration | Topical use |

Dosage and administration details:

Application on the face once daily

| | |
|--|------------------------------|
| Investigational medicinal product name | Dermotivin® Soft Liquid soap |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cutaneous liquid |
| Routes of administration | Topical use |

Dosage and administration details:

Application on the face twice daily (morning/evening)

| | |
|--|--|
| Investigational medicinal product name | Cetaphil® Dermacontrol Moisturizer SPF30 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |

Dosage and administration details:

Application on the face once daily (evening)

| | |
|---------------------------------------|-------------------|
| Number of subjects in period 1 | Treatment regimen |
| Started | 50 |
| Completed | 46 |
| Not completed | 4 |
| Adverse event, non-fatal | 3 |
| Subject's request | 1 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|-------------------|
| Reporting group title | Treatment regimen |
|-----------------------|-------------------|

Reporting group description: -

| Reporting group values | Treatment regimen | Total | |
|--|-------------------|-------|--|
| Number of subjects | 50 | 50 | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 21 | 21 | |
| Adults (18-64 years) | 29 | 29 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 21.8 | | |
| standard deviation | ± 8 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 33 | 33 | |
| Male | 17 | 17 | |
| Skin phototype | | | |
| Units: Subjects | | | |
| Phototype I | 1 | 1 | |
| Phototype II | 25 | 25 | |
| Phototype III | 21 | 21 | |
| Phototype IV | 3 | 3 | |
| Investigator Global Assessment | | | |
| Units: Subjects | | | |
| Mild | 37 | 37 | |
| Moderate | 13 | 13 | |
| Severe | 0 | 0 | |
| Acne duration | | | |
| Units: Years | | | |
| arithmetic mean | 9.8 | | |
| standard deviation | ± 7.4 | - | |
| Total lesions count | | | |
| Units: Lesion | | | |
| arithmetic mean | 97 | | |
| standard deviation | ± 45.6 | - | |
| Non-Inflammatory lesions | | | |

| | | | |
|----------------------|--------|---|--|
| Units: Lesions | | | |
| arithmetic mean | 68.1 | | |
| standard deviation | ± 37.2 | - | |
| Inflammatory Lesions | | | |
| Units: Lesions | | | |
| arithmetic mean | 28.9 | | |
| standard deviation | ± 21.7 | - | |

End points

End points reporting groups

| | |
|--|--------------------|
| Reporting group title | Treatment regimen |
| Reporting group description: - | |
| Subject analysis set title | Treatment regimen |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| This population consists of the Intent-to-Treat population, after exclusion of subjects who never took the treatment with certainty based on the monitoring report | |

Primary: Subject Overall satisfaction with the three-part treatment regimen

| | |
|---|---|
| End point title | Subject Overall satisfaction with the three-part treatment regimen ^[1] |
| End point description: | |
| Percentage of subjects satisfied and very satisfied with the three-part treatment regimen | |
| End point type | Primary |
| End point timeframe: | |
| Week 12 | |
| Notes: | |

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: it is an open label study, no inferential statistics have been performed. All variables have been descriptively summarized on ITT population and on safety population.

| End point values | Treatment regimen | | | |
|-----------------------------|-------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 48 | | | |
| Units: Percent subjects | | | | |
| number (not applicable) | 90 | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Week 12

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

Dictionary used

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

| | |
|--------------------|----|
| Dictionary version | 18 |
|--------------------|----|

Reporting groups

| | |
|-----------------------|--------------------|
| Reporting group title | Overall population |
|-----------------------|--------------------|

Reporting group description: -

| Serious adverse events | Overall population | | |
|---|--------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Immune system disorders | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

Frequency threshold for reporting non-serious adverse events: 2 %

| Non-serious adverse events | Overall population | | |
|---|--------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 13 / 50 (26.00%) | | |
| Injury, poisoning and procedural complications | | | |

| | | | |
|--|---------------------|--|--|
| Laceration subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | | |
| Radius fracture subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | | |
| Eye disorders Blepharitis subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | | |
| Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | | |
| Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | | |
| Rash subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | | |
| Skin exfoliation subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | | |
| Skin irritation subjects affected / exposed occurrences (all) | 3 / 50 (6.00%) 3 | | |
| Musculoskeletal and connective tissue disorders Tenosynovitis subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | | |
| Infections and infestations Herpes simplex subjects affected / exposed occurrences (all) | 1 / 50 (2.00%) 1 | | |
| Impetigo | | | |

| | | | |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 1 / 50 (2.00%) | | |
| occurrences (all) | 1 | | |
| Mucosal infection | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | | |
| occurrences (all) | 1 | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 4 / 50 (8.00%) | | |
| occurrences (all) | 4 | | |
| Pharyngitis | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | | |
| occurrences (all) | 1 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported