



Clinical trial results:

Multi-centre, randomized, double-blind, active- and vehiclecontrolled trial to compare the efficacy and safety of tretinoin clindamycin phosphate gel to clindamycin phosphate gel alone, tretinoin gel alone, and vehicle in the treatment of acne vulgaris in patients from 12 to less than 18 years of age.

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2010-022918-15 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 21 October 2003 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 29 July 2016 |
| First version publication date | 29 July 2016 |

Trial information

Trial identification

| | |
|-----------------------|-----------------|
| Sponsor protocol code | 7001-G2HP-07-02 |
|-----------------------|-----------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Dow Pharmaceutical Sciences |
| Sponsor organisation address | 127 Hospital Drive, #202, Vallejo, United States, CA 94589 |
| Public contact | Group leader study manager, Meda Pharma GmbH & Co. KG, +49 6172 888 01, 42b@medapharma.de |
| Scientific contact | Head of Corporate Clinical Affairs, Meda Pharma GmbH & Co. KG, +49 6172 888 01, 42b@medapharma.de |

Notes:

Paediatric regulatory details

| | |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMA-000892-PIP01-10 |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | Yes |
| 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 | 28 January 2004 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 21 October 2003 |
| Global end of trial reached? | Yes |
| Global end of trial date | 21 October 2003 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To compare the efficacy and safety of Clin-RA Gel to Clindamycin phosphate 1.2% Gel alone, Tretinoin 0.025% Gel alone, and Clin-RA Gel vehicle in the treatment of acne vulgaris.

Protection of trial subjects:

No specific additional measures to minimise pain and distress were required. The subjects could withdraw from treatment at any time and for any reason.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 11 February 2003 |
| 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 | United States: 1288 |
| Worldwide total number of subjects | 1288 |
| EEA total number of subjects | 0 |

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) | 2 |
| Adolescents (12-17 years) | 793 |
| Adults (18-64 years) | 493 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Male or female subjects of any race, 12 years of age or older, with acne vulgaris, presenting with 20-50 inflammatory lesions (papules and pustules), 20-100 non-inflammatory lesions (open and closed comedones), and < 2 nodules.

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | overall trial (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 | Clin-RA |

Arm description: -

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | Clindamycin phosphate 1.2% and Tretinoin 0.025% |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Gel |
| Routes of administration | Topical use |

Dosage and administration details:

Clin-RA Gel (Clindamycin phosphate 1.2% and Tretinoin 0.025%)

Dosing: Once-a-day application (at bedtime)

Mode of Administration: Topically applied to the face

| | |
|------------------|-------------|
| Arm title | Clindamycin |
|------------------|-------------|

Arm description: -

| | |
|--|----------------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Clindamycin phosphate 1.2% |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Gel |
| Routes of administration | Topical use |

Dosage and administration details:

Clindamycin phosphate 1.2% (in same vehicle as investigational product)

Dosing: Once-a-day application (at bedtime)

Mode of Administration: Topically applied to the face

| | |
|------------------|-----------|
| Arm title | Tretinoin |
|------------------|-----------|

Arm description: -

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Tretinoin 0.025% |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Gel |
| Routes of administration | Topical use |

Dosage and administration details:

Tretinoin 0.025% (in same vehicle as investigational product)

Dosing: Once-a-day application (at bedtime)

Mode of Administration: Topically applied to the face

| | |
|--|---------------|
| Arm title | Vehicle |
| Arm description: - | |
| Arm type | Vehicle |
| Investigational medicinal product name | N/A (vehicle) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Gel |
| Routes of administration | Topical use |

Dosage and administration details:

Dosing: Once-a-day application (at bedtime)

Mode of Administration: Topically applied to the face

| Number of subjects in period 1 | Clin-RA | Clindamycin | Tretinoin |
|---------------------------------------|---------|-------------|-----------|
| Started | 425 | 218 | 429 |
| Completed | 352 | 183 | 347 |
| Not completed | 73 | 35 | 82 |
| Adverse event, non-fatal | 5 | 1 | 3 |
| Other | 3 | 2 | 5 |
| Inappropriate enrollment | 1 | 1 | 2 |
| Subject request | 27 | 11 | 21 |
| Lost to follow-up | 29 | 18 | 33 |
| Pregnancy | - | - | 2 |
| Protocol deviation | 3 | - | 6 |
| Lack of efficacy | 5 | 2 | 10 |

| Number of subjects in period 1 | Vehicle |
|---------------------------------------|---------|
| Started | 216 |
| Completed | 173 |
| Not completed | 43 |
| Adverse event, non-fatal | 1 |
| Other | 3 |
| Inappropriate enrollment | 2 |
| Subject request | 14 |
| Lost to follow-up | 15 |
| Pregnancy | - |
| Protocol deviation | 1 |
| Lack of efficacy | 7 |

Baseline characteristics

Reporting groups

| | |
|--------------------------------|-------------|
| Reporting group title | Clin-RA |
| Reporting group description: - | |
| Reporting group title | Clindamycin |
| Reporting group description: - | |
| Reporting group title | Tretinoin |
| Reporting group description: - | |
| Reporting group title | Vehicle |
| Reporting group description: - | |

| Reporting group values | Clin-RA | Clindamycin | Tretinoin |
|---|---------|-------------|-----------|
| Number of subjects | 425 | 218 | 429 |
| Age categorical Units: Subjects | | | |
| In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over | | | |
| Age continuous Units: years | | | |
| arithmetic mean | 19.22 | 19.25 | 19.38 |
| standard deviation | ± 8.01 | ± 8.11 | ± 8.14 |
| Gender categorical Units: Subjects | | | |
| Female | 235 | 111 | 236 |
| Male | 190 | 107 | 193 |

| Reporting group values | Vehicle | Total | |
|--|---------|--------------------------------------|--|
| Number of subjects | 216 | 1288 | |
| Age categorical Units: Subjects | | | |
| In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years | | 0 0 0 0 0 0 0 0 | |

| | | | |
|-------------------|--|---|--|
| 85 years and over | | 0 | |
|-------------------|--|---|--|

| | | | |
|--------------------|--------|-----|--|
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 19.04 | | |
| standard deviation | ± 7.82 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 110 | 692 | |
| Male | 106 | 596 | |

End points

End points reporting groups

| | |
|--------------------------------|-------------|
| Reporting group title | Clin-RA |
| Reporting group description: - | |
| Reporting group title | Clindamycin |
| Reporting group description: - | |
| Reporting group title | Tretinoin |
| Reporting group description: - | |
| Reporting group title | Vehicle |
| Reporting group description: - | |

Primary: Dichotomized Evaluator's Global Severity Score / Week 12

| | |
|------------------------|--|
| End point title | Dichotomized Evaluator's Global Severity Score / Week 12 |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| Week 12 | |

| End point values | Clin-RA | Clindamycin | Tretinoin | Vehicle |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 425 | 218 | 429 | 216 |
| Units: Success, Failure | | | | |
| Success | 95 | 38 | 60 | 16 |
| Failure | 330 | 180 | 369 | 200 |

Statistical analyses

| | |
|---|-------------------------|
| Statistical analysis title | Clin-RA vs. Clindamycin |
| Comparison groups | Clin-RA v Clindamycin |
| Number of subjects included in analysis | 643 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.122 |
| Method | Cochran-Mantel-Haenszel |

| | |
|----------------------------|-----------------------|
| Statistical analysis title | Clin-RA vs. Tretinoin |
| Comparison groups | Clin-RA v Tretinoin |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 854 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|-------------------------|
| Statistical analysis title | Clin-RA vs. Vehicle |
| Comparison groups | Clin-RA v Vehicle |
| Number of subjects included in analysis | 641 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Primary: Percent Change from Baseline in Inflammatory Lesion Count / Week 12 | |
| End point title | Percent Change from Baseline in Inflammatory Lesion Count / Week 12 |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| Baseline and week 12 | |

| End point values | Clin-RA | Clindamycin | Tretinoin | Vehicle |
|-------------------------------|--------------------|--------------------|------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 425 | 218 | 429 | 216 |
| Units: percent change | | | | |
| median (full range (min-max)) | 61.3 (-425 to 100) | 52.1 (-250 to 100) | 50 (-164 to 100) | 38.9 (-100 to 100) |

Statistical analyses

| | |
|---|-------------------------|
| Statistical analysis title | Clin-RA vs. Clindamycin |
| Comparison groups | Clin-RA v Clindamycin |
| Number of subjects included in analysis | 643 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.02 |
| Method | Ranked ANOVA |

| | |
|---|-----------------------|
| Statistical analysis title | Clin-RA vs. Tretinoin |
| Comparison groups | Tretinoin v Clin-RA |
| Number of subjects included in analysis | 854 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Ranked ANOVA |

| | |
|---|---------------------|
| Statistical analysis title | Clin-RA vs. Vehicle |
| Comparison groups | Clin-RA v Vehicle |
| Number of subjects included in analysis | 641 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Ranked ANOVA |

Primary: Percent Change from Baseline in Non-inflammatory Lesion Count / Week 12

| | |
|------------------------|---|
| End point title | Percent Change from Baseline in Non-inflammatory Lesion Count / Week 12 |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| Baseline and week 12. | |

| End point values | Clin-RA | Clindamycin | Tretinoin | Vehicle |
|-------------------------------|--------------------|--------------------|------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 425 | 218 | 429 | 216 |
| Units: percent change | | | | |
| median (full range (min-max)) | 42.3 (-238 to 100) | 32.2 (-195 to 100) | 40 (-326 to 100) | 24.2 (-198 to 100) |

Statistical analyses

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Clin-RA vs. Clindamycin |
| Comparison groups | Clin-RA v Clindamycin |

| | |
|---|---------------|
| Number of subjects included in analysis | 643 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.088 |
| Method | Ranked ANOVA |

| | |
|---|-----------------------|
| Statistical analysis title | Clin-RA vs. Tretinoin |
| Comparison groups | Clin-RA v Tretinoin |
| Number of subjects included in analysis | 854 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.11 |
| Method | Ranked ANOVA |

| | |
|---|---------------------|
| Statistical analysis title | Clin-RA vs. Vehicle |
| Comparison groups | Clin-RA v Vehicle |
| Number of subjects included in analysis | 641 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Ranked ANOVA |

Primary: Percent Change from Baseline in Total Lesion Count / Week 12

| | |
|------------------------|--|
| End point title | Percent Change from Baseline in Total Lesion Count / Week 12 |
| End point description: | |
| | |
| End point type | Primary |
| End point timeframe: | |
| Baseline and week 12. | |

| End point values | Clin-RA | Clindamycin | Tretinoin | Vehicle |
|-------------------------------|--------------------|-------------------|--------------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 425 | 218 | 429 | 216 |
| Units: percent change | | | | |
| median (full range (min-max)) | 48.4 (-245 to 100) | 40.9 (-117 to 98) | 39.7 (-150 to 100) | 25 (-164 to 100) |

Statistical analyses

| | |
|---|-------------------------|
| Statistical analysis title | Clin-RA vs. Clindamycin |
| Comparison groups | Clin-RA v Clindamycin |
| Number of subjects included in analysis | 643 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.018 |
| Method | Ranked ANOVA |

| | |
|---|-----------------------|
| Statistical analysis title | Clin-RA vs. Tretinoin |
| Comparison groups | Clin-RA v Tretinoin |
| Number of subjects included in analysis | 854 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.002 |
| Method | Ranked ANOVA |

| | |
|---|---------------------|
| Statistical analysis title | Clin-RA vs. Vehicle |
| Comparison groups | Clin-RA v Vehicle |
| Number of subjects included in analysis | 641 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Ranked ANOVA |

Adverse events

Adverse events information

Timeframe for reporting adverse events:
until 30 days post-treatment

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

Dictionary used

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

| | |
|--------------------|-----|
| Dictionary version | 6.1 |
|--------------------|-----|

Reporting groups

| | |
|-----------------------|-------------|
| Reporting group title | Clin RA Gel |
|-----------------------|-------------|

Reporting group description:

Clindamycin phosphate 1.2% and Tretinoin 0.025%

| | |
|-----------------------|-----------|
| Reporting group title | Tretinoin |
|-----------------------|-----------|

Reporting group description:

Tretinoin 0.025% (in same vehicle as investigational product)

| | |
|-----------------------|---------|
| Reporting group title | Vehicle |
|-----------------------|---------|

Reporting group description:

Clin-RA Gel Vehicle

| | |
|-----------------------|-------------|
| Reporting group title | Clindamycin |
|-----------------------|-------------|

Reporting group description:

Clindamycin phosphate 1.2% (in same vehicle as investigational product)

| Serious adverse events | Clin RA Gel | Tretinoin | Vehicle |
|---|-----------------|-----------------|-----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 425 (0.24%) | 2 / 429 (0.47%) | 2 / 216 (0.93%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 425 (0.00%) | 0 / 429 (0.00%) | 1 / 216 (0.46%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Pregnancy | | | |
| subjects affected / exposed | 0 / 425 (0.00%) | 1 / 429 (0.23%) | 0 / 216 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Cholethiasis | | | |

| | | | |
|---|--|-----------------|-----------------|
| subjects affected / exposed | 1 / 425 (0.24%) | 0 / 429 (0.00%) | 0 / 216 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Abnormal behaviour | Additional description: Hospitalization due to increase in behavior disorder | | |
| subjects affected / exposed | 0 / 425 (0.00%) | 1 / 429 (0.23%) | 1 / 216 (0.46%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|--|--|--|
| Serious adverse events | Clindamycin | | |
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 218 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 218 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Pregnancy | | | |
| subjects affected / exposed | 0 / 218 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatobiliary disorders | | | |
| Cholethiasis | | | |
| subjects affected / exposed | 0 / 218 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Psychiatric disorders | | | |
| Abnormal behaviour | Additional description: Hospitalization due to increase in behavior disorder | | |
| subjects affected / exposed | 0 / 218 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| Non-serious adverse events | Clin RA Gel | Tretinoin | Vehicle |
|---|--------------------|--------------------|-------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 117 / 425 (27.53%) | 127 / 429 (29.60%) | 46 / 216 (21.30%) |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 8 / 425 (1.88%) | 8 / 429 (1.86%) | 3 / 216 (1.39%) |
| occurrences (all) | 8 | 8 | 3 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 10 / 425 (2.35%) | 12 / 429 (2.80%) | 3 / 216 (1.39%) |
| occurrences (all) | 10 | 12 | 3 |
| Cough | | | |
| subjects affected / exposed | 2 / 425 (0.47%) | 9 / 429 (2.10%) | 0 / 216 (0.00%) |
| occurrences (all) | 2 | 9 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 7 / 425 (1.65%) | 10 / 429 (2.33%) | 3 / 216 (1.39%) |
| occurrences (all) | 7 | 10 | 3 |
| Pharyngolaryngeal pain | | | |
| subjects affected / exposed | 6 / 425 (1.41%) | 3 / 429 (0.70%) | 5 / 216 (2.31%) |
| occurrences (all) | 6 | 3 | 5 |
| Sinusitis | | | |
| subjects affected / exposed | 4 / 425 (0.94%) | 9 / 429 (2.10%) | 2 / 216 (0.93%) |
| occurrences (all) | 4 | 9 | 2 |
| Skin and subcutaneous tissue disorders | | | |
| Sunburn | | | |
| subjects affected / exposed | 6 / 425 (1.41%) | 11 / 429 (2.56%) | 1 / 216 (0.46%) |
| occurrences (all) | 6 | 11 | 1 |

| Non-serious adverse events | Clindamycin | | |
|---|-------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 59 / 218 (27.06%) | | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 6 / 218 (2.75%) | | |
| occurrences (all) | 6 | | |

| | | | |
|---|----------------------|--|--|
| Respiratory, thoracic and mediastinal disorders | | | |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 6 / 218 (2.75%) 6 | | |
| Cough subjects affected / exposed occurrences (all) | 4 / 218 (1.83%) 4 | | |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 3 / 218 (1.38%) 3 | | |
| Pharyngolaryngeal pain subjects affected / exposed occurrences (all) | 0 / 218 (0.00%) 0 | | |
| Sinusitis subjects affected / exposed occurrences (all) | 2 / 218 (0.92%) 2 | | |
| Skin and subcutaneous tissue disorders | | | |
| Sunburn subjects affected / exposed occurrences (all) | 3 / 218 (1.38%) 3 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---------------|---|
| 06 March 2003 | Implemented changes to study procedures and analyses requested by the FDA |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported