



Clinical trial results:

Subject adherence and satisfaction for treatment of Onychomycosis with Loceryl® Nail Lacquer 5% versus Canesten® Fungal Nail Treatment Set

Summary

| | |
|--------------------------|-------------------|
| EudraCT number | 2015-001503-31 |
| Trial protocol | IS |
| Global end of trial date | 14 September 2016 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 12 June 2020 |
| First version publication date | 12 June 2020 |

Trial information

Trial identification

| | |
|-----------------------|------------------|
| Sponsor protocol code | RD.03.SPR.105078 |
|-----------------------|------------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02705664 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | GALDERMA R&D |
| Sponsor organisation address | Les Templiers, 2400, Route des Colles, Biot, France, 06410 |
| Public contact | Clinical Project Manager, Galderma R&D, +33 493957051, farzaneh.sidou@galderma.com |
| Scientific contact | Clinical Project Manager, Galderma R&D, +33 493957051, farzaneh.sidou@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 | 15 March 2017 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 14 September 2016 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to compare subject-reported ease of use, adherence, and satisfaction with the following two treatments of Distal and Lateral Subungual Onychomycosis (DLSO) in toenails: Loceryl Nail Lacquer (Loceryl) and Canesten Fungal Nail Treatment Set (Urea 40% ointment and Bifonazole cream). The safety of these treatments was also evaluated.

Protection of trial subjects:

The study sponsor and any third party to whom aspects of the study management or monitoring have been delegated will undertake their assigned roles for this study in compliance with all applicable industry regulations and ICH Good Clinical Practice (GCP) Guideline E6 (1996) and EU Directive 2001/20/EC.

Background therapy: -

Evidence for comparator: -

| | |
|---|-----------------|
| Actual start date of recruitment | 18 January 2016 |
| 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 | Iceland: 22 |
| Worldwide total number of subjects | 22 |
| EEA total number of subjects | 22 |

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) | 0 |
| Adults (18-64 years) | 16 |
| From 65 to 84 years | 6 |

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

Subject disposition

Recruitment

Recruitment details:

The study was conducted at a single center in Iceland between 18 January 2016 (first subject screened) to 14 September 2016 (last subject completed).

Pre-assignment

Screening details:

A total of 22 subjects with mycologically confirmed Distal and Lateral Subungual Onychomycosis (DLSO) (positive direct microscopy and culture results) were enrolled and randomized to treatment. Out of them 20 subjects had completed and 2 subjects requested early discontinued from the study.

Period 1

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

Arms

| | |
|-----------|---|
| Arm title | Loceryl plus Canesten Fungal Nail Treatment Set |
|-----------|---|

Arm description:

Each subject received 2 topical treatments with Loceryl in one foot and Canesten in the opposite foot. Loceryl (amorolfine hydrochloride 5 percent [%]) nail lacquer was applied once weekly for 7 weeks over the great toenail of all affected toenails in the evening (at bed time).

Canesten (Urea ointment + Bifonazole cream) was applied once daily in the evening (at bedtime), in two phases: Phase 1 and Phase 2 on all affected toenails (including great toenail) of the opposite foot.

Phase I, Canesten Urea ointment was applied under occlusion for 2-3 weeks, depending on the success of removal of the diseased great toenail plates.

Phase II, Canesten Bifonazole cream was applied for 4 weeks, after the maximum 3- week treatment period with Canesten Urea ointment.

At the end of the study, subjects were provided with Loceryl at their request to complete treatment of their DLSO.

| | |
|--|-----------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Amorolfine Hydrochloride 5% |
| Investigational medicinal product code | |
| Other name | Loceryl® |
| Pharmaceutical forms | Medicated nail lacquer |
| Routes of administration | Topical use |

Dosage and administration details:

Amorolfine hydrochloride 5 % nail lacquer was applied once weekly, topically over the entire toenail plate of all affected toenails in the evening (at bed time) for a duration of 7 weeks.

| | |
|--|-------------|
| Investigational medicinal product name | Bifonazole |
| Investigational medicinal product code | |
| Other name | Canesten® |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |

Dosage and administration details:

Canesten Bifonazole cream was applied once daily over the affected toenails of opposite foot in the evening (at bed time) for 4 weeks.

| | |
|--|-------------|
| Investigational medicinal product name | Urea 40% |
| Investigational medicinal product code | |
| Other name | Canesten® |
| Pharmaceutical forms | Ointment |
| Routes of administration | Topical use |

Dosage and administration details:

Canesten Urea ointment was applied once daily over the affected toenails of opposite foot in the evening (at bed time) for 2-3 weeks.

| Number of subjects in period 1 | Loceryl plus Canesten Fungal Nail Treatment Set |
|---------------------------------------|---|
| Started | 22 |
| Completed | 20 |
| Not completed | 2 |
| Premature discontinuation | 2 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|--------------------------------|
| Reporting group title | Overall Study (overall period) |
|-----------------------|--------------------------------|

Reporting group description: -

| Reporting group values | Overall Study (overall period) | Total | |
|------------------------------------|-----------------------------------|-------|--|
| Number of subjects | 22 | 22 | |
| Age categorical Units: Subjects | | | |

| | | | |
|---|----------------|----|--|
| Age continuous Units: years arithmetic mean standard deviation | 55.3 ± 12.6 | - | |
| Gender categorical Units: Subjects | | | |
| Female | 5 | 5 | |
| Male | 17 | 17 | |
| Race Units: Subjects | | | |
| White | 22 | 22 | |

End points

End points reporting groups

| | |
|-----------------------|---|
| Reporting group title | Loceryl plus Canesten Fungal Nail Treatment Set |
|-----------------------|---|

Reporting group description:

Each subject received 2 topical treatments with Loceryl in one foot and Canesten in the opposite foot. Loceryl (amorolfine hydrochloride 5 percent [%]) nail lacquer was applied once weekly for 7 weeks over the great toenail of all affected toenails in the evening (at bed time).

Canesten (Urea ointment + Bifonazole cream) was applied once daily in the evening (at bedtime), in two phases: Phase 1 and Phase 2 on all affected toenails (including great toenail) of the opposite foot.

Phase I, Canesten Urea ointment was applied under occlusion for 2-3 weeks, depending on the success of removal of the diseased great toenail plates.

Phase II, Canesten Bifonazole cream was applied for 4 weeks, after the maximum 3- week treatment period with Canesten Urea ointment.

At the end of the study, subjects were provided with Loceryl at their request to complete treatment of their DLSO.

| | |
|----------------------------|---------|
| Subject analysis set title | Loceryl |
|----------------------------|---------|

| | |
|---------------------------|--------------------|
| Subject analysis set type | Intention-to-treat |
|---------------------------|--------------------|

Subject analysis set description:

Subjects received Amorolfine hydrochloride 5 % nail lacquer was applied once weekly, topically over the entire toenail plate of all affected toenails in the evening (at bed time) for a duration of 7

| | |
|----------------------------|----------|
| Subject analysis set title | Canesten |
|----------------------------|----------|

| | |
|---------------------------|--------------------|
| Subject analysis set type | Intention-to-treat |
|---------------------------|--------------------|

Subject analysis set description:

Subject received Canesten (Urea ointment + Bifonazole cream) was applied once daily in the evening (at bedtime), in two phases: Phase 1 and Phase 2 on all affected toenails (including great toenail) of the opposite foot.

Phase I, Canesten Urea ointment was applied under occlusion for 2-3 weeks, depending on the success of removal of the diseased great toenail plates.

Phase II, Canesten Bifonazole cream was applied for 4 weeks, after the maximum 3- week treatment period with Canesten Urea ointment

Primary: Number of Subjects who Preferred for Study Treatment at End of Phase I

| | |
|-----------------|---|
| End point title | Number of Subjects who Preferred for Study Treatment at End of Phase I ^[1] |
|-----------------|---|

End point description:

Number of subjects who preferred a study treatment over the other at the end of Phase 1 were reported. Intent-to-Treat (ITT) population consisted of all subjects enrolled and randomized. Here, "N" number of subjects analyzed signifies subjects who were evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From start of study treatment up to Week 7

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: The data presented for this primary endpoint is based on a subject questionnaire regarding ease of use of the study products and satisfaction with treatment procedures. So, the statistical comparisons could not be presented.

| | | | | |
|------------------------------|---|--|--|--|
| End point values | Loceryl plus Canesten Fungal Nail Treatment Set | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 20 | | | |
| Units: Subjects | | | | |
| Canesten better than Loceryl | 2 | | | |

| | | | | |
|------------------------------|----|--|--|--|
| Loceryl better than Canesten | 18 | | | |
|------------------------------|----|--|--|--|

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects who Preferred for Study Treatment at End of Phase II

| | |
|-----------------|--|
| End point title | Number of Subjects who Preferred for Study Treatment at End of Phase II ^[2] |
|-----------------|--|

End point description:

Number of subjects who preferred a study treatment over the other at the end of Phase 2 were reported. ITT population consisted of all subjects enrolled and randomized. Here, "N" number of subjects analyzed signifies subjects who were evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From start of study up to Week 7

Notes:

[2] - 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: The data presented for this primary endpoint is not analysed by the reporting arms. So, the statistical comparisons could not be presented.

| | | | | |
|------------------------------|---|--|--|--|
| End point values | Loceryl plus Canesten Fungal Nail Treatment Set | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 21 | | | |
| Units: Subjects | | | | |
| Canesten better than Loceryl | 3 | | | |
| Loceryl better than Canesten | 18 | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Reported Subject Questionnaire at the End of Phase I

| | |
|-----------------|--|
| End point title | Number of Subjects Reported Subject Questionnaire at the End of Phase I ^[3] |
|-----------------|--|

End point description:

Subject questionnaire for the ease of use of the study products and satisfaction with treatment procedures as reported by subjects at the end of Phase I was assessed. Subject satisfaction questionnaire consisted of 12 questions (Q): Q1: How easy was it to treat your toenails, Q2: Satisfied with frequency of application, Q3: Overall, how easy to use did you find the treatment, Q4: Forgot to use it, Q5: Away from home, Q6: Did not have time to apply, Q7: Did not see any result, Q8: Grew tired of applying the treatment, Q9: Local tolerance, Q10: Procedure too difficult to follow, Q11: Local side effects further to application of the treatment, Q12: Overall, how satisfied with the treatment. ITT population consisted of all subjects enrolled and randomized. Here 'N' (number of subjects analyzed) signifies subjects who were evaluable for this endpoint and 'n' (number analyzed) signifies number of subjects who were evaluable for each specified category.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Week 3

Notes:

[3] - 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: The data presented for this primary endpoint is based on a subject questionnaire regarding ease of use of the study products and satisfaction with treatment procedures. So, the statistical comparisons could not be presented.

| End point values | Loceryl | Canesten | | |
|------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 22 | 22 | | |
| Units: Subjects | | | | |
| Q1: Easy (n=22, 22) | 4 | 6 | | |
| Q1: Fairly easy (n=22, 22) | 1 | 10 | | |
| Q1: Not easy (n=22, 22) | 1 | 2 | | |
| Q2: Very satisfied (n=22, 22) | 16 | 4 | | |
| Q1: Very easy (n=22, 22) | 16 | 4 | | |
| Q2: Satisfied (n=22, 22) | 5 | 8 | | |
| Q2: Some what satisfied (n=22, 22) | 0 | 6 | | |
| Q2: Not satisfied (n=22, 22) | 1 | 4 | | |
| Q3: Very easy (n=22, 22) | 15 | 2 | | |
| Q3: Easy (n=22, 22) | 6 | 8 | | |
| Q3: Fairly easy (n=22, 22) | 1 | 9 | | |
| Q3: Not easy (n=22, 22) | 0 | 3 | | |
| Q4: No (n=9, 9) | 8 | 7 | | |
| Q4: Yes (n=9, 9) | 1 | 2 | | |
| Q5: No (n=9, 9) | 7 | 5 | | |
| Q5: Yes (n=9, 9) | 2 | 4 | | |
| Q6: No (n=9, 9) | 9 | 6 | | |
| Q6: Yes (n=9, 9) | 0 | 3 | | |
| Q7: No (n=9, 9) | 9 | 9 | | |
| Q7: Yes (n=9, 9) | 0 | 0 | | |
| Q8: No (n=9, 9) | 9 | 7 | | |
| Q8: Yes (n=9, 9) | 0 | 2 | | |
| Q9: No (n=9, 9) | 9 | 8 | | |
| Q9: Yes (n=9, 9) | 0 | 1 | | |
| Q10: No (n=9, 9) | 9 | 7 | | |
| Q10: Yes (n=9, 9) | 0 | 2 | | |
| Q11: Not at all (n=22, 22) | 21 | 16 | | |
| Q11: Somewhat (n=22, 22) | 1 | 6 | | |
| Q12: Very satisfied (n=22, 22) | 13 | 9 | | |
| Q12: Satisfied (n=22, 22) | 7 | 9 | | |
| Q12: Somewhat satisfied (n=22, 22) | 2 | 3 | | |
| Q12: Notsatisfied (n=22, 22) | 0 | 1 | | |

Statistical analyses

Primary: Number of Subjects Reported Subject Questionnaire at the End of Phase II

| | |
|-----------------|---|
| End point title | Number of Subjects Reported Subject Questionnaire at the End of Phase II ^[4] |
|-----------------|---|

End point description:

Subject questionnaire for the ease of use of the study products and satisfaction with treatment procedures as reported by subjects at the end of Phase 2 was assessed. Subject satisfaction questionnaire consisted of 14 questions (Q): Q1: How easy was it to treat your toenails, Q2: Satisfied with frequency of application, Q3: Overall, how easy to use did you find the treatment, Q4: Forgot to use it, Q5: Away from home, Q6: Did not have time to apply, Q7: Did not see any result, Q8: Grew tired of applying the treatment, Q9: Local tolerance, Q10: Procedure too difficult to follow, Q11: Local side effects further to application of the treatment, Q12: Overall, how satisfied with the treatment, Q13: Recommend the use of study treatment, Q14: Continue to use Loceryl 7 to 10 months / Use Canesten again. ITT population was analysed. Here 'N' signifies subjects who were evaluable for this endpoint and 'n' signifies number of subjects who were evaluable for each specified category.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Week 7

Notes:

[4] - 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: The data presented for this primary endpoint is based on a subject questionnaire regarding ease of use of the study products and satisfaction with treatment procedures. So, the statistical comparisons could not be presented.

| End point values | Loceryl | Canesten | | |
|------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 20 | 20 | | |
| Units: Subjects | | | | |
| Q1: Very easy (n=20, 20) | 13 | 14 | | |
| Q1: Easy (n=20, 20) | 6 | 3 | | |
| Q1: Fairly easy (n=20, 20) | 1 | 2 | | |
| Q1: Not easy (n=20, 20) | 0 | 1 | | |
| Q2: Very satisfied (n=20, 20) | 14 | 5 | | |
| Q2: Satisfied (n=20, 20) | 5 | 9 | | |
| Q2: Some what satisfied (n=20, 20) | 1 | 5 | | |
| Q2: Not satisfied (n=20, 20) | 0 | 1 | | |
| Q3: Very easy (n=20, 20) | 16 | 8 | | |
| Q3: Easy (n=20, 20) | 3 | 7 | | |
| Q3: Fairly easy (n=20, 20) | 1 | 4 | | |
| Q3: Not easy (n=20, 20) | 0 | 1 | | |
| Q4: No (n=7, 7) | 6 | 3 | | |
| Q4: Yes (n=7, 7) | 1 | 4 | | |
| Q5: No (n=7, 7) | 3 | 3 | | |
| Q5: Yes (n=7, 7) | 4 | 4 | | |
| Q6: No (n=7, 7) | 7 | 6 | | |
| Q6: Yes (n=7, 7) | 0 | 1 | | |
| Q7: No (n=7, 7) | 7 | 7 | | |
| Q7: Yes (n=7, 7) | 0 | 0 | | |
| Q8: No (n=7, 7) | 7 | 6 | | |
| Q8: Yes (n=7, 7) | 0 | 1 | | |
| Q9: No (n=7, 7) | 7 | 7 | | |
| Q9: Yes (n=7, 7) | 0 | 0 | | |
| Q10: No (n=7, 7) | 7 | 7 | | |

| | | | | |
|------------------------------------|----|----|--|--|
| Q10: Yes (n=7, 7) | 0 | 0 | | |
| Q11: Not at all (n=20, 20) | 19 | 17 | | |
| Q11: Somewhat (n=20, 20) | 1 | 3 | | |
| Q12: Very satisfied (n=20, 20) | 13 | 8 | | |
| Q12: Satisfied (n=20, 20) | 7 | 10 | | |
| Q12: Somewhat satisfied (n=20, 20) | 0 | 2 | | |
| Q13: Yes (n=19, 19) | 19 | 17 | | |
| Q13: No (n=19, 19) | 0 | 2 | | |
| Q14: Yes (n=20, 20) | 20 | 17 | | |
| Q13: No (n=20, 20) | 0 | 3 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Adherence Rate to Study Product Applications

| | |
|---|---|
| End point title | Number of Subjects with Adherence Rate to Study Product Applications ^[5] |
| End point description: Adherence rate was subject's adherence in terms of applications was reported. ITT population consisted of all subjects enrolled and randomized. | |
| End point type | Primary |
| End point timeframe: Week 7 | |

Notes:

[5] - 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: The data presented for this primary endpoint is not analysed by the reporting arms. So, the statistical comparisons could not be presented.

| End point values | Loceryl | Canesten | | |
|-----------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 22 | 22 | | |
| Units: Subjects | | | | |
| Adherence rate: No | 4 | 9 | | |
| Adherence rate: Yes | 18 | 13 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Adherence Rate to Nail Preparation Procedures

| | |
|---|--|
| End point title | Number of Subjects with Adherence Rate to Nail Preparation Procedures ^[6] |
| End point description: Adherence rate was subject's adherence with the nail preparation procedures was reported. ITT population consisted of all subjects enrolled and randomized. | |
| End point type | Primary |

End point timeframe:

Week 3

Notes:

[6] - 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: The data presented for this primary endpoint is not analysed by the reporting arms. So, the statistical comparisons could not be presented.

| End point values | Loceryl | Canesten | | |
|-----------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 22 | 22 | | |
| Units: Subjects | | | | |
| Adherence rate: No | 3 | 17 | | |
| Adherence rate: Yes | 19 | 5 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Local tolerance Assessment: Erythema Score at Week 7

| | |
|-----------------|---|
| End point title | Local tolerance Assessment: Erythema Score at Week 7 ^[7] |
|-----------------|---|

End point description:

Local tolerance for erythema was assessed on the treated area at each post baseline visit. Safety population consists of the Intent-to-Treat population, after exclusion of subjects who never used the treatment with certainty based on monitoring report. Here, "N" number of subjects analyzed signifies subjects who were evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Up to Week 7

Notes:

[7] - 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: No statistical analysis was performed for this endpoint, only descriptive analysis were reported.

| End point values | Loceryl | Canesten | | |
|--------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 21 | 21 | | |
| Units: score on the scale | | | | |
| arithmetic mean (standard deviation) | 0.0 (± 0.0) | 0.0 (± 0.2) | | |

Statistical analyses

No statistical analyses for this end point

Primary: Local tolerance Assessment: Irritation Score at Week 7

| | |
|-----------------|---|
| End point title | Local tolerance Assessment: Irritation Score at Week 7 ^[8] |
|-----------------|---|

End point description:

Local tolerance for irritation was assessed on the treated area at each post baseline visit. Safety population consists of the Intent-to-Treat population, after exclusion of subjects who never used the treatment with certainty based on monitoring report. Here, "N" number of subjects analyzed signifies subjects who were evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Up to Week 7

Notes:

[8] - 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: No statistical analysis was performed for this endpoint, only descriptive analysis were reported.

| End point values | Loceryl | Canesten | | |
|--------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 21 | 21 | | |
| Units: score on the scale | | | | |
| arithmetic mean (standard deviation) | 0.0 (± 0.0) | 0.0 (± 0.0) | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Adverse Events

| | |
|-----------------|---|
| End point title | Number of Subjects with Adverse Events ^[9] |
|-----------------|---|

End point description:

Adverse event (AE) was any untoward medical occurrence in a subject or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. AE can be any unfavorable and/or unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal/investigational product, whether or not related to the medicinal/investigational products or to the study procedures.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From start of study drug administration up to Week 7

Notes:

[9] - 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: No statistical analysis was performed for this endpoint, only descriptive analysis were reported.

| End point values | Loceryl plus Canesten Fungal Nail Treatment Set | | | |
|-----------------------------|--|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 22 | | | |
| Units: Subjects | 3 | | | |

Statistical analyses

Primary: Subjects Reported Satisfaction Questionnaire (How much time to apply treatment) at the End of Phase I

| | |
|-----------------|---|
| End point title | Subjects Reported Satisfaction Questionnaire (How much time to apply treatment) at the End of Phase I |
|-----------------|---|

End point description:

Subject questionnaire for the ease of use of the study products and satisfaction with treatment procedures as reported by subjects at the end of Phase I was assessed. Subject satisfaction questionnaire consisted of how much time to apply treatment. ITT population consisted of all subjects enrolled and randomized. Here, "N" number of subjects analyzed signifies subjects who were evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Week 3

| End point values | Loceryl | Canesten | | |
|--------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 22 | 22 | | |
| Units: minute | | | | |
| arithmetic mean (standard deviation) | 12.4 (± 7.9) | 22.3 (± 8.1) | | |

Statistical analyses

| | |
|---|-------------------------|
| Statistical analysis title | Loceryl Versus Canesten |
| Comparison groups | Loceryl v Canesten |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | McNemar |

Primary: Subjects Reported Satisfaction Questionnaire (How much time to apply treatment) at the End of Phase II

| | |
|-----------------|--|
| End point title | Subjects Reported Satisfaction Questionnaire (How much time to apply treatment) at the End of Phase II |
|-----------------|--|

End point description:

Subject questionnaire for the ease of use of the study products and satisfaction with treatment procedures as reported by subjects at the end of Phase 2 was assessed. Subject satisfaction questionnaire consisted of how much time to apply treatment. ITT population consisted of all subjects enrolled and randomized. Here, "N" number of subjects analyzed signifies subjects who were evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Week 7

| End point values | Loceryl | Canesten | | |
|--------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 20 | 20 | | |
| Units: minute | | | | |
| arithmetic mean (standard deviation) | 10.3 (± 8.8) | 7.6 (± 5.8) | | |

Statistical analyses

| Statistical analysis title | Loceryl Versus Canesten |
|---|-------------------------|
| Comparison groups | Loceryl v Canesten |
| Number of subjects included in analysis | 40 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.113 |
| Method | McNemar |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From start of study drug administration up to Week 7

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

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

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

Reporting groups

| | |
|-----------------------|--------------|
| Reporting group title | All Subjects |
|-----------------------|--------------|

Reporting group description:

Each subject received 2 topical treatments with Loceryl in one foot and Canesten in the opposite foot. Loceryl (amorolfine hydrochloride 5 percent [%]) nail lacquer was applied once weekly for 7 weeks over the great toenail of all affected toenails in the evening (at bed time).

Canesten (Urea ointment + Bifonazole cream) was applied once daily in the evening (at bedtime), in two phases: Phase 1 and Phase 2 on all affected toenails (including great toenail) of the opposite foot. Phase I, Canesten Urea ointment was applied under occlusion for 2-3 weeks, depending on the success of removal of the diseased great toenail plates. Phase II, Canesten Bifonazole cream was applied for 4 weeks, after the maximum 3- week treatment period with Canesten Urea ointment.

At the end of the study, subjects was provided with Loceryl at their request to complete treatment of their DLSO.

| Serious adverse events | All Subjects | | |
|---|----------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

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

| Non-serious adverse events | All Subjects | | |
|---|-----------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 3 / 22 (13.64%) | | |
| Injury, poisoning and procedural complications | | | |
| Clavicle fracture | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | | |
| occurrences (all) | 1 | | |
| General disorders and administration site conditions | | | |
| Influenza like illness | | | |

| | | | |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 2 / 22 (9.09%) | | |
| occurrences (all) | 2 | | |

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