



Clinical trial results:

Traitment of recessive nonbullous congenital ichthyosis with topic Epigallocatechin.

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2009-013656-77 |
| Trial protocol | FR |
| Global end of trial date | 25 March 2013 |

Results information

| | |
|--------------------------------|----------------|
| Result version number | v1 (current) |
| This version publication date | 14 August 2022 |
| First version publication date | 14 August 2022 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | 09-PP-02 |
|-----------------------|----------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | chu de nice |
| Sponsor organisation address | DRCI-Hôpital de Cimiez - 4 avenue reine victoria, Nice, France, 06003 |
| Public contact | Christine Chiaverini, CHU de Nice Dermatology, chiaverini.c@chu-nice.fr |
| Scientific contact | Christine Chiaverini, CHU de Nice Dermatology, chiaverini.c@chu-nice.fr |

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 | 25 March 2013 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 25 March 2013 |
| Global end of trial reached? | Yes |
| Global end of trial date | 25 March 2013 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The principal objective of this trial is the evaluation of the topic Polyphenon E(R) efficacy in order to ameliorate the skin desquamation and the skin roughness in lamellar ichthyosis patients after 4 weeks of treatment.

Protection of trial subjects:

Patients of both sexes of at least 8 years with a clinical diagnosis of lamellar ichthyosis and scores of roughness and desquamation of intensity moderated in severe on every side of the body after the obtaining informed consent from parents

Background therapy: -

Evidence for comparator: -

| | |
|---|-----------------|
| Actual start date of recruitment | 28 October 2010 |
| 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 | France: 6 |
| Worldwide total number of subjects | 6 |
| EEA total number of subjects | 6 |

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) | 6 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

6 patients with lamellar ichthyosis will be included in the trial. After selection, they will be seen in inclusion visit. After inclusion, the localization of test area will be decided and the side to treat with VEREGEN 10% will be randomized. Patient will be seen every week for 4 weeks for clinical evaluation of assessment criteria by an independent

Pre-assignment

Screening details:

- Patients of both sexes of at least 8 years and less than 65 years.
- Patients with a clinical diagnosis of LI

Pre-assignment period milestones

| | |
|------------------------------|---|
| Number of subjects started | 6 |
| Number of subjects completed | 6 |

Period 1

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

Arms

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

Arm description:

After selection, they will be seen in inclusion visit. After inclusion, the localization of test area will be decided and the side to treat with VEREGEN 10% will be randomized. Patient will be seen every week for 4 weeks for clinical evaluation of assessment criteria by an independent assessor. According to the randomisation he will apply VEREGEN® 10 % on a randomized area and the moisturizing cream of the other side. If there is an improvement of at least a test zone he will enter in the follow-up period for 8 weeks.

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | VEREGEN 10% |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical use |

Dosage and administration details:

Apply about an 0.5 cm strand of the Veregen® to each wart using the finger(s) during 8 weeks

| Number of subjects in period 1 | Treatment |
|---------------------------------------|-----------|
| Started | 6 |
| Completed | 6 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|------------------|
| Reporting group title | Inclusion Period |
|-----------------------|------------------|

Reporting group description: -

| Reporting group values | Inclusion Period | Total | |
|---|------------------|-------|--|
| Number of subjects | 6 | 6 | |
| 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) | 6 | 6 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 0 | 0 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 3 | 3 | |
| Male | 3 | 3 | |

End points

End points reporting groups

| Reporting group title | Treatment |
|--|-----------|
| Reporting group description: | |
| After selection, they will be seen in inclusion visit. After inclusion, the localization of test area will be decided and the side to treat with VEREGEN 10% will be randomized. Patient will be seen every week for 4 weeks for clinical evaluation of assessment criteria by an independent assessor. According to the randomisation he will apply VEREGEN ® 10 % on a randomized area and the moisturizing cream of the other side. If there is an improvement of at least a test zone he will enter in the follow-up period for 8 weeks. | |

Primary: patients' rate with a decrease of roughness and cutaneous desquamation score of at least 2 points at the end of the treatment (4 weeks).

| End point title | patients' rate with a decrease of roughness and cutaneous desquamation score of at least 2 points at the end of the treatment (4 weeks). ^[1] |
|-----------------|---|
|-----------------|---|

End point description:

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

End point timeframe:

After traitement : one time

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: Patients of this trial will be analyzed in intention to treat (ITT), every patient will be analyzed according to the results of the randomisation whatever is the effectively treated zone and the therapeutic observance. An analysis per protocol will be also realized whose results will not substitute themselves for the results of the analysis in ITT. We remind that considering the gravity of this pathology, the absence of effective treatment and the hoped implication by patient's associations, num

| End point values | Treatment | | | |
|-----------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 6 | | | |
| Units: Number | 6 | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Each visit

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

Dictionary used

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

| | |
|--------------------|----|
| Dictionary version | 12 |
|--------------------|----|

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: There are no non-serious events

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