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 Dermatolgy, chiaverini.c@chu-nice.fr
Scientific contact	Christine Chiaverini, CHU de Nice Dermatolgy, 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) efficacity in order to ameliorate the skin desquamation and the skin roughness in lamellar ichthysosis patients after 4 weeks of traitment.

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 independe

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: Eache 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