Clinical trial results:
Vitiligo en het Koebnerfenomeen.
(Vitiligo inductie- en therapie model : klinische en immunologische analyse)

Summary

EudraCT number	2009-017425-19
Trial protocol	BE
Global end of trial date	15 September 2015

Results information

Result version number	v1 (current)
This version publication date	08 August 2024
First version publication date	08 August 2024
Summary attachment (see zip file)	Final Study Report (2009-017425-19 Final study report.pdf)

Trial information

Trial identification

Sponsor protocol code	AGO/2009/012

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Ghent University Hospital
Sponsor organisation address	Corneel Heymanslaan 10, Ghent, Belgium, 9000
Public contact	Hiruz CTU, University Hospital Ghent, 32 93320500, hiruz.ctu@uzgent.be
Scientific contact	Hiruz CTU, University Hospital Ghent, 32 93320500, hiruz.ctu@uzgent.be

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	02 November 2011
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 September 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Analysis of clinical and immunological processes that arise during the induction phase of vitiligo and the influence of topical therapies on this process.

Protection of trial subjects:

Ethics review and approval, informed consent, supportive care and routine monitoring.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 January 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	Belgium: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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)	12
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

14 patients were screened in the period from dd-mmm-yyyy till dd-mmm-yyyy. 14 patients were included, Y patients were randomised. 12 patients were included and completed the trial. End of trial notification was dated 15-09-2015 (last patient last visit) and submitted to EC and CA 28-03-2019.

Pre-assignment

Screening details:

Inclusion criteria:
PART I and II
- Extensive form of vitiligo (> 50% BSA) or vitiligo patients who are under depigmenting / decolouring treatment
- Patients who request depigmenting therapy
- ≥ 18 years
- Not pregnant

PART III
- Patients without vitiligo who come to the dermatology department for consultation
- ≥ 18 years
- Not pregnant

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Assessor[1]

Blinding implementation details:

Blinding of the assessor: the clinical evaluation (percentage depigmentation versus pigmentation) will take place based on clinical photos. The assessment of histological material will be based on Skin sections.
The assessor is a person who will not receive information about the intervention.
Only after completion of the assessment will the randomization code be broken.
The creams will be applied ad randomly to one of the selected test zones.
Randomization will take place using a draw system

Arms

Are arms mutually exclusive?	No
Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Vaseline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

N/A

Arm title	tacrolimus treatment

Arm description: -

Arm type	Active comparator

Investigational medicinal product name	Tacrolimus
Investigational medicinal product code	CAS 104987-11-3
Other name	Protopic
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

Maximum duration of treatment of a subject according to the protocol: 10 days
Maximum dose allowed: once a day,
Dose per day 0,1 % percent
4 applications (day 1,day 3, day 6 and day 10)

Arm title	pimecrolimus treatment

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Pimecrolimus
Investigational medicinal product code	CAS 137071-32-0
Other name	Elidel
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

Maximum duration of treatment of a subject according to the protocol: 10 days
Maximum dose allowed: once a day,
Dose per day, 1% percent.
4 applications (day 1, day 3, day 6 and day 10)

Arm title	cortisone treatment

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	cortisone
Investigational medicinal product code	CAS 13609671
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

Maximum duration of treatment of a subject according to the protocol: protocol
Maximum dose allowed: once a day
Dose per day 1 mg/g milligram(s)/gram
4 applications (day 1, day 3, day 6 and day 10)

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: See attachment Final Study Report

Number of subjects in period 1	Placebo	tacrolimus treatment	pimecrolimus treatment
Started	3	3	3
Completed	3	3	3

Number of subjects in period 1	cortisone treatment
Started	3
Completed	3

Baseline characteristics

Reporting groups[1]	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	tacrolimus treatment
Reporting group description: -	
Reporting group title	pimecrolimus treatment
Reporting group description: -	
Reporting group title	cortisone treatment
Reporting group description: -	

Notes:

[1] - The number of subjects reported to be in the baseline period is not equal to the worldwide number of subjects enrolled in the trial. It is expected that these numbers will be the same.
Justification: In total, five patients met the inclusion criteria of our study; however, two patients declined to be enrolled because of logistic reasons. All remaining three patients completed the intervention and the follow-up as planned. All participants were included in the main analysis. Age-eligible participants were recruited among patients attending our clinic for a visit at the time of the inclusion period.

Reporting group values	Placebo	tacrolimus treatment	pimecrolimus treatment
Number of subjects	3	3	3
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	3	3
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	3	3	3
Male	0	0	0
Ethnic origin Units: Subjects			
Surinamese	1	1	1
Caucasian	1	1	1
North African	1	1	1
skin type Units: Subjects			
type 2	1	1	1
type 5	1	1	1
type 4	1	1	1
Total extent depigmentations (BSA, body surface area) Units: Subjects			
BSA 60 %	1	1	1

BSA 70 %	1	1	1
BSA 65%	1	1	1

Reporting group values	cortisone treatment	Total	
Number of subjects	3	3	
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)	0	0	
Adults (18-64 years)	3	3	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	3	3	
Male	0	0	
Ethnic origin Units: Subjects			
Surinamese	1	1	
Caucasian	1	1	
North African	1	1	
skin type Units: Subjects			
type 2	1	1	
type 5	1	1	
type 4	1	1	
Total extent depigmentations (BSA, body surface area) Units: Subjects			
BSA 60 %	1	1	
BSA 70 %	1	1	
BSA 65%	1	1	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: -	
Reporting group title	tacrolimus treatment
Reporting group description: -	
Reporting group title	pimecrolimus treatment
Reporting group description: -	
Reporting group title	cortisone treatment
Reporting group description: -	

Primary: percentage of skin pigmentation in the treated area

End point title	percentage of skin pigmentation in the treated area[1]

End point description:

End point type	Primary

End point timeframe:

1 month

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: See attachment Final Study Report

End point values	Placebo	tacrolimus treatment	pimecrolimus treatment	cortisone treatment
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: pigmentation (%)				
arithmetic mean (standard deviation)	3 (± 3)	3 (± 3)	3 (± 3)	3 (± 3)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
Overall study	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	12.1

Reporting groups	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Treatment
Reporting group description: -	

Serious adverse events	Placebo	Treatment	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	Placebo	Treatment	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	

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: No non-serious adverse events were recorded for the participating patients.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 February 2010	Amendment 1: Reasons for the substantial amendment: - Choice of local corticosteroid was changed from Locoid cream to Elocom cream - Modification of inclusion and exclusion criteria Brief description of the changes: - Choice of local corticosteroid was changed from Locoid cream to Elocom cream - As a result of the decision to include only adult patients in the study, the inclusion and exclusion criteria were modified so that only patients aged 18 years or older will be able to participate in the study
02 April 2010	Amendment 2: Reasons for the substantial amendment: - Change in the taking of biopsies on day 3, 10, 30 and 60 - Change in the number of applications of the products Brief description of the changes: - Change in the taking of biopsies on day 3, 10, 30 and 60 - Change in the number of applications of the products
26 September 2012	Amendment 3: Comments/explanation/reasons for substantial amendment: - The research project was expanded to include a 2nd and a 3rd research part (parts 2 and 3). In part 1, cream therapies with an active ingredient will be evaluated in patients with vitiligo. On the control areas, vaseline will no longer be used but a neutral moisturizing cream without an active ingredient (Cold Cream Lipo Cream from Fagron). In this part 1, there will also be control zones where no cream therapy will be applied. In part 2 of the study, we will mainly focus on the control group from part 1. This part of the study will consist of an additional group of vitiligo patients, where no additional cream therapy or only a cream therapy without active ingredient (moisturizer, Cold Cream Lipo cream) will be applied after the elicitation test. In part 3, we will focus on a control group that will consist of patients without vitiligo, on whom we will only do the vitiligo elicitation tests in order to induce a skin reaction - the number of subjects who participate in this study was changed: part 1: 15 patients part 2: 20 patients part 3: 10 patients - Vaseline will no longer be used on the control areas but a neutral moisturizing cream without active ingredient: Cold Cream Lipo Cream from Fagron.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/21982055