Clinical trial results:
A Blinded, Prospective, Randomised, Placebo-Controlled, Multi-Centre, Split-Face Study of Photodynamic Therapy With Metvix 160 mg/g Cream in Subjects With Acne Vulgaris.

Summary

EudraCT number	2004-002367-24
Trial protocol	SE
Global end of trial date	02 May 2005

Results information

Result version number	v1 (current)
This version publication date	02 July 2022
First version publication date	02 July 2022

Trial information

Trial identification

Sponsor protocol code	PC TA001/04

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Galderma R&D SNC
Sponsor organisation address	Les templiers, 2400 Routes des colles, Biot, France, 06410
Public contact	CTA Coordinator, Galderma R&D SNC, +33 (0)493-95-70-85, cta.coordinator@galderma.com
Scientific contact	CTA Coordinator, Galderma R&D SNC, +33 (0)493-95-70-85, cta.coordinator@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	02 May 2005
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	02 May 2005
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of the trial was to evaluate efficacy and safety of photodynamic therapy (PDT) with Metvix 160 mg/g cream compared to placebo in subjects with moderate inflammatory acne vulgaris in the face.

Protection of trial subjects:

Subject protection was ensured by following high medical and ethical standards in accordance with the principles laid down in the Declaration of Helsinki, and that are consistent with Good Clinical Practice and applicable regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2004
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	Norway: 18
Country: Number of subjects enrolled	Sweden: 12
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	30
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 30 subjects was enrolled in the study from 3 sites in Europe.

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	Metvix® PDT

Arm description:

Subjects were given 4 tubes of of Metvix cream. Each tube contain 2 grams of cream. The cream was applied evenly in thin manner on and left for 3 hours (Treatment 1 on Week 1 and Treatment 2 on Week 2). Illumination started immediately after removal of the dressing and the cream from the skin. The side of the face were the cream was applied first did preferably receive illumination first. The average time needed for a light dose of 37 J/cm2 was about 8 minutes.

Arm type	Experimental
Investigational medicinal product name	Metvix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	External use

Dosage and administration details:

Metvix cream applied on skin for 3 hours.

Arm title	Placebo Matched Metvix

Arm description:

Subjects were given 4 tubes of of Placebo cream. Each tube contain 2 grams of cream. The cream was applied evenly in thin manner and left for 3 hours (Treatment 1 on Week 1 and Treatment 2 on Week 2). Illumination started immediately after removal of the dressing and the cream from the skin. The side of the face were the cream was applied first did preferably receive illumination first. The average time needed for a light dose of 37 J/cm2 was about 8 minutes.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Metvix® PDT	Placebo Matched Metvix
Started	30	30
Completed	27	27
Not completed	3	3
Adverse Events	3	3

Baseline characteristics

Reporting groups	
Reporting group title	Overall study

Reporting group description: -

Reporting group values	Overall study	Total	
Number of subjects	30	30	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	19		
standard deviation	± 3	-	
Gender categorical Units: Subjects			
Female	5	5	
Male	25	25	
Race Units: Subjects			
Caucasian	30	30	

End points

End points reporting groups

Reporting group title	Metvix® PDT

Reporting group description:

Subjects were given 4 tubes of of Metvix cream. Each tube contain 2 grams of cream. The cream was applied evenly in thin manner on and left for 3 hours (Treatment 1 on Week 1 and Treatment 2 on Week 2). Illumination started immediately after removal of the dressing and the cream from the skin. The side of the face were the cream was applied first did preferably receive illumination first. The average time needed for a light dose of 37 J/cm2 was about 8 minutes.

Reporting group title	Placebo Matched Metvix

Reporting group description:

Subjects were given 4 tubes of of Placebo cream. Each tube contain 2 grams of cream. The cream was applied evenly in thin manner and left for 3 hours (Treatment 1 on Week 1 and Treatment 2 on Week 2). Illumination started immediately after removal of the dressing and the cream from the skin. The side of the face were the cream was applied first did preferably receive illumination first. The average time needed for a light dose of 37 J/cm2 was about 8 minutes.

Primary: Percent Change From Baseline in Inflammatory Lesions Counts to Visit 7

End point title	Percent Change From Baseline in Inflammatory Lesions Counts to Visit 7[1]

End point description:

Inflationary lesions included Papules a small, solid elevation less than one centimetre in diameter. Pustules a small, circumscribed elevation of the skin, which contains yellow-white exudate. Nodules/Cysts a circumscribed, elevated, lesion generally more than 1.0 cm in diameter. Intent to Treat population that consisted of the entire population enrolled and randomised. Intent to treat analysis population was used for this outcome.

End point type	Primary

End point timeframe:

Visit 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: Only descriptive summary statistics was planned for this endpoint.

End point values	Metvix® PDT	Placebo Matched Metvix		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: Percent change				
arithmetic mean (standard deviation)	45.7 (± 34.5)	26.6 (± 38.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With an Investigator's Global Assessment (IGA)

Score of 0 to 4

End point title	Number of Subjects With an Investigator's Global Assessment (IGA) Score of 0 to 4

End point description:

IGA was an assessment scale used to evaluate facial acne severity. IGA was recorded from components collected on the case report form (CRF) using a 5-point scale where (0 = clear; 1 = almost clear; 2 = mild; 3 = moderate; 4 = severe) based on inflammation, pustules and papulation/infiltration. Higher score indicates severity of disease. ITT population was used for this analysis.

End point type	Secondary

End point timeframe:

At Visit 1, 4, 6 and 7

End point values	Metvix® PDT	Placebo Matched Metvix		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: subjects				
Visit 1: Clear	0	0		
Visit 1: Almost clear	0	0		
Visit 1: Mild	0	0		
Visit 1: Moderate	24	23		
Visit 1: Severe	6	7		
Visit 4: Clear	0	0		
Visit 4: Almost clear	1	1		
Visit 4: Mild	11	7		
Visit 4: Moderate	16	17		
Visit 4: Severe	2	5		
Visit 6: Clear	0	0		
Visit 6: Almost clear	10	4		
Visit 6: Mild	8	7		
Visit 6: Moderate	12	17		
Visit 6: Severe	0	2		
Visit 7: Clear	1	0		
Visit 7: Almost clear	18	3		
Visit 7: Mild	12	13		
Visit 7: Moderate	8	11		
Visit 7: Severe	1	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Adverse Event

End point title	Number of Subjects with Adverse Event[2]

End point description:

An adverse event (AE) was any untoward medical occurrence in a clinical investigation subjects administered a product; the event did not need to have a causal relationship with the treatment. TEAEs were AEs that occurred following the start of treatment or AEs increasing in severity during treatment.

End point type	Secondary

End point timeframe:

Baseline up to approximately 1 year

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only arm applicable for this endpoint is reported.

End point values	Metvix® PDT			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: subjects	21			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Non-Inflammatory Lesions Counts at Visit 7

End point title	Number of Subjects With Non-Inflammatory Lesions Counts at Visit 7

End point description:

Non - inflammatory lesions included: Open Comedones - A mass of sebaceous material that is impacted behind an open follicular orifice (blackhead). Closed Comedone - A mass of sebaceous material that is impacted behind a closed follicular orifice
(whitehead). Analysis was performed on ITT population.

End point type	Secondary

End point timeframe:

Visit 7

End point values	Metvix® PDT	Placebo Matched Metvix		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: Subjects	30	30		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Baseline up to 1 year	
Adverse event reporting additional description:	
Safety population that included all subjects included in this study received at least one PDT treatment and all subjects are therefore included in the safety population.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups	
Reporting group title	Overall subjects

Reporting group description: -

Serious adverse events	Overall subjects		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	Overall subjects		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 30 (70.00%)		
Skin and subcutaneous tissue disorders			
PAIN OF SKIN			
subjects affected / exposed	20 / 30 (66.67%)		
occurrences (all)	20		
ERYTHEMA			
subjects affected / exposed	18 / 30 (60.00%)		
occurrences (all)	18		
SKIN SWELLING			
subjects affected / exposed	11 / 30 (36.67%)		
occurrences (all)	11		
DERMATITIS EXFOLIATIVE NOS			

subjects affected / exposed	7 / 30 (23.33%)		
occurrences (all)	7		
ACNE AGGRAVATED			
subjects affected / exposed	4 / 30 (13.33%)		
occurrences (all)	4		
DRY SKIN			
subjects affected / exposed	2 / 30 (6.67%)		
occurrences (all)	2		
CELLULITIS			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
SKIN TENDERNESS			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
SCAB			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
BLISTER			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		

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