Clinical trial results:
Safety Dermatological Evaluation: genital mucosa irritation - Product tested: Dermacyd PH_DETINLYN Tangerine Mix.

Summary

EudraCT number	2014-004664-38
Trial protocol	Outside EU/EEA
Global end of trial date	22 September 2008

Results information

Result version number	v1 (current)
This version publication date	01 April 2016
First version publication date	16 May 2015

Trial information

Trial identification

Sponsor protocol code	LACAC_L_04304

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00785642
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Sanofi-aventis Farmacêutica Ltda
Sponsor organisation address	Avenida Major Sylvio de Magalhães Padilha, Sao Paulo, Brazil, 5.200
Public contact	Trial Tranparency Team, Sanofi Aventis Recherche & Developpement, contact-us@sanofi.com
Scientific contact	Trial Tranparency Team, Sanofi Aventis Recherche & Developpement, contact-us@sanofi.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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	23 September 2008
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 September 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To prove the safety of the gynecological formulation in normal and usual use conditions.

Protection of trial subjects:

The study was conducted by investigators experienced in the treatment of pediatric subjects. The parent(s) or guardian(s) as well as the children were fully informed of all pertinent aspects of the clinical trial as well as the possibility to discontinue at any time. A consent form was signed by the parent(s)/guardian(s).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 August 2008
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	Brazil: 31
Worldwide total number of subjects	31
EEA total number of subjects	0

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)	11
Adolescents (12-17 years)	17
Adults (18-64 years)	3
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was performed in one center in Brazil. A total of 31 subjects were enrolled on 28 Auguest 2008

Pre-assignment

Screening details:

NA

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Lactic acid

Arm description:

Lactic Acid on the external genital area for 21 days

Arm type	Experimental
Investigational medicinal product name	Lactic Acid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Vaginal liquid
Routes of administration	Topical use

Dosage and administration details:

Liquid soap applied in the external genital area, in small quantity, with abundantly rinse after use.

Number of subjects in period 1	Lactic acid
Started	31
Completed	30
Not completed	1
Lost to follow-up	1

Baseline characteristics

Reporting groups	
Reporting group title	Lactic acid
Reporting group description:	
Lactic Acid on the external genital area for 21 days	

Reporting group values	Lactic acid	Total	
Number of subjects	31	31	
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)	11	11	
Adolescents (12-17 years)	17	17	
Adults (18-64 years)	3	3	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	31	31	
Male	0	0	

End points

End points reporting groups

Reporting group title	Lactic acid

Reporting group description:

Lactic Acid on the external genital area for 21 days

Primary: Number of subjects with skin reaction in the tested region

End point title	Number of subjects with skin reaction in the tested region[1]

End point description:

Level of skin irritation in the tested region, evaluated by the presence of erythema, edema, desquamation, vesiculation, ardor and itching and their intensity (mild, moderate, severe) and causality (not related, possible related, probably related or definitely related).

End point type	Primary

End point timeframe:

21 Days

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: Statistical analysis plan included only descriptive statistics.

End point values	Lactic acid			
Subject group type	Reporting group			
Number of subjects analysed	30[2]			
Units: Subject				
erythema	0			
edema	0			
desquamation	0			
vesiculation	0			
ardor	0			
itching	0			

Notes:

[2] - One subject did not return for final evaluation.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

21 Days

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	NA

Reporting groups

Reporting group title	Lactic acid

Reporting group description:

All subjects who were exposed to Lactic Acid.

Serious adverse events	Lactic acid		
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	Lactic acid		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 30 (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 adverse event was reported during the trial.

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