



Clinical trial results:

VERSATIS - Efficacité et tolérance d'emplâtres de lidocaïne à 5% (Versatis® 5%) dans les douleurs neuropathiques et dans les douleurs de crises vaso-occlusives drépanocytaires de l'enfant, de l'adolescent et du jeune adulte

VERSATIS - Lidocaïne 5% plasters (Versatis® 5%) in pediatric neuropathic pains and vasoocclusive sickle cell crisis pain

Summary

EudraCT number	2010-023461-22
Trial protocol	FR
Global end of trial date	27 March 2014

Results information

Result version number	v1 (current)
This version publication date	13 March 2021
First version publication date	13 March 2021
Summary attachment (see zip file)	Publication Versatis (VERSATIS_ROUSSEAU et al_Accepted article.pdf)

Trial information

Trial identification

Sponsor protocol code	ET2010-077
-----------------------	------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01314300
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Centre Léon Bérard
Sponsor organisation address	28 rue Laennec, LYON, France, 69008
Public contact	Centre Léon Bérard, Centre Léon Bérard, 33 478782968, DRCIreglementaire@lyon.unicancer.fr
Scientific contact	Dr Perrine MAREC-BERARD, Dr Perrine MAREC-BERARD, 33 478782828, DRCIreglementaire@lyon.unicancer.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	15 December 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 March 2014
Global end of trial reached?	Yes
Global end of trial date	27 March 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Estimer l'efficacité à 12 heures de Versatis® 5% sur la réduction des douleurs neuropathiques pures ou mixtes et sur la réduction des douleurs de crises vaso-occlusives drépanocytaires, localisées, superficielles, chez l'enfant, l'adolescent et le jeune adulte

Proportion of patients with a significant pain score decrease i.e. difference in VAS pain score of at least two points between t0 and t12 (12h-VAS \geq 2p-decrease) during at least two out of the three consecutive days of treatment.

Protection of trial subjects:

Within the framework of this study, the patients included will be followed according to the recommendations for the management of pain. The pain score was assessed by a 100 mm-Visual Analogue Score (VAS) self-assessment graduated from 0 (no pain) to 10 (maximal pain) at patch application (t0), at 6 hours (t6), and at 12 hours (t12) post application during three consecutive days. The analgesic treatments prescribed before the inclusion was not changed during the three days of evaluation unless absolutely required. In case of significant increase in pain during the three days (i.e. at least two points increasing in VAS score), the use of additional level II or level III analgesics, antiepileptics, or antidepressants was allowed and collected.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 July 2011
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: 39
Worldwide total number of subjects	39
EEA total number of subjects	39

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)	13
Adolescents (12-17 years)	13
Adults (18-64 years)	13
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

France

1st inclusion : 05/07/2011

Last patient last visit : 27/03/2014

Pre-assignment

Screening details:

Children and young adults aged from 6 to 21 years old suffering from either neuropathic pain in an oncologic setting, or localized and superficial pain due to vaso-occlusive bone crises in sickle-cell patients, insufficiently relieved by the commonly used treatments were eligible. The DN4 score had to be ≥ 4 .

Period 1

Period 1 title	Treatment (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Experimental
-----------	--------------

Arm description:

Efficacy of lidocaine 5% plaster

Treatment of pain by lidocaine 5% plaster

Arm type	Experimental
Investigational medicinal product name	Lidocaïne 5% plaster
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous patch
Routes of administration	Cutaneous use

Dosage and administration details:

The lidocaine 5% patches (Versatis®, Grünenthal GmbH, Aachen, Germany) for cutaneous application consists of a hydrogel base stuck to a polyethylene terephthalate support covered with a protective film of polyethylene terephthalate.²² Each plaster, supplied in 10 by 14cm size and containing 700 mg of lidocaine, was applied to the painful area (the most painful one in case of several painful areas) for 12 hours per day (12 hours application then 12 hours without patch), and for at least three consecutive days. The patch was applied on intact skin, not irritated, not injured, to more thoroughly cover the painful area with the number of patches defined according to the size of the painful area and the patient's body surface

Number of subjects in period 1	Experimental
Started	39
Completed	39

Baseline characteristics

Reporting groups

Reporting group title	Treatment
Reporting group description: -	

Reporting group values	Treatment	Total	
Number of subjects	39	39	
Age categorical			
The mean age was 12.7 ±3.5 years			
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)	19	19	
Adolescents (12-17 years)	20	20	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
The mean age was 12.7 ±3.5 years			
Units: years			
arithmetic mean	12.7		
standard deviation	± 3.5	-	
Gender categorical			
Units: Subjects			
Female	21	21	
Male	18	18	

End points

End points reporting groups

Reporting group title	Experimental
Reporting group description:	
Efficacy of lidocaine 5% plaster	
Treatment of pain by lidocaine 5% plaster	

Primary: Pain score

End point title	Pain score ^[1]
End point description:	
Proportion of patients with a significant pain score decrease i.e. difference in VAS pain score of at least two points between t0 and t12 (12h-VAS \geq 2p-decrease) during at least two out of the three consecutive days of treatment	
End point type	Primary
End point timeframe:	
12 hours	

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: No possibility of size the type of statistical analyse : the sample size was calculated using the Fleming-A'hern single-stage design²³ assuming that the proportion of patients with a 12h-VAS \geq 2p-decrease during at least two of the three consecutive days following patch application should result in at least 60%. A rate of 60% or less would mean that the benefit in pain relief is not confirmed. Assuming a 5% one-sided alpha and 85% power, 39 patients had to be enrolled. A minimum of 29 successes w

End point values	Experimental			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: hours	39			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

The investigator collects (spontaneous patient report or questioning) and immediately notifies the sponsor of all SAEs, in a written report, whether or not they are deemed to be attributable to research and which occur during the study

Adverse event reporting additional description:

3 (7.7%, 95%CI [1.6%-20.9%]) patients experienced at least one grade 1 or 2 adverse event with only two events possibly related to the patch application (one localized erythema and one pruritus at the application site). One generalized skin eruption was recorded but assessed as unlikely related to treatment. No serious adverse event was observed.

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

Dictionary used

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

Dictionary version	21.0
--------------------	------

Frequency threshold for reporting non-serious adverse events: 5 %

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: 3 (7.7%, 95%CI [1.6%-20.9%]) patients experienced at least one grade 1 or 2 adverse event with only two events possibly related to the patch application (one localized erythema and one pruritus at the application site). One generalized skin eruption was recorded but assessed as unlikely related to treatment. No serious adverse event was observed

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 November 2011	modification of criteria inclusion + prolongation of inclusion period

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported