



Clinical trial results:

Treprostinil Iontophoresis : a Pharmacodynamic and Pharmacokinetic Study

Summary

EudraCT number	2011-003401-21
Trial protocol	FR
Global end of trial date	31 August 2015

Results information

Result version number	v1 (current)
This version publication date	25 June 2022
First version publication date	25 June 2022
Summary attachment (see zip file)	Tipps (2011-003401-21) - results (Roustit and Cracowski_Cutaneous Iontophoresis of Treprostinil in Systemic Sclerosis CPT 2014 +suppl online.pdf)

Trial information

Trial identification

Sponsor protocol code	11PHR02
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01554540
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	CHUGA
Sponsor organisation address	CS10217, GRENOBLE, France,
Public contact	M.Roustit, CIC, mroustit@chu-grenoble.fr
Scientific contact	M.Roustit, DCIC, mroustit@chu-grenoble.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	26 July 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 January 2013
Global end of trial reached?	Yes
Global end of trial date	31 August 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Déterminer l'effet pharmacodynamique du tréprostinil administré par iontophorèse cutanée chez le volontaire sain, au niveau de la pulpe des doigts.

Protection of trial subjects:

projet ayant reçu l'avis favorable d'un comité de protection des personnes / favorable advice of IRB in France

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 January 2012
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: 60
Worldwide total number of subjects	60
EEA total number of subjects	60

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)	57
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Critères d'inclusion:

Volontaires sains : Première partie

- Age de 18 ans au moins
- Personne affilié à la sécurité sociale ou bénéficiaire d'un tel régime
- Formulaire de consentement signé

Patients : Seconde partie

- Age de 18 ans au moins
- Personne affilié à la sécurité sociale ou bénéficiaire d'un tel régime
- Formulaire de consentement

Period 1

Period 1 title	Study period
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	treprostinil
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	tteprostinil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Transdermal solution
Routes of administration	Iontophoresis

Dosage and administration details:

different dosage

Number of subjects in period 1	treprostinil
Started	60
Completed	60

Period 2

Period 2 title	NaCL
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	NaCL
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	NaCL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Transdermal solution
Routes of administration	Iontophoresis

Dosage and administration details:

2,56.10⁻⁴ M

Number of subjects in period 2	NaCL
Started	60
Completed	60

Baseline characteristics

End points

End points reporting groups

Reporting group title	treprostinil
Reporting group description: -	
Reporting group title	NaCL
Reporting group description: -	

Primary: primary

End point title	primary
End point description:	
End point type	Primary
End point timeframe:	
Aire sous la courbe de l'augmentation de flux cutané 10 heures (AUC0-10) après iontophorèse de tréprostinil (2,56.10 ⁻⁴ M ; 20 min jusqu'à 0,1mA.cm ⁻²) évaluée en imagerie laser speckle, comparée à l'iontophorèse de chlorure de sodium (NaCl).	

End point values	treprostinil	NaCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60	60		
Units: AUC				
number (not applicable)	23066.1	11187.1		

Statistical analyses

Statistical analysis title	primary end point
Statistical analysis description:	
L'amplitude de la réponse à l'iontophorèse de tréprostinil en aire sous la courbe (AUC0-10) sera comparée celle de NaCl par un test de t apparié si les données suivent une loi normale. Un test de Wilcoxon sera réalisé dans le cas contraire. Les tests seront réalisés après correction de Bonferroni pour comparaisons multiples	
Comparison groups	treprostinil v NaCL
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.05
Method	t-test, 2-sided
Parameter estimate	AUC

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Les effets indésirables graves seront notifiés jusqu'à 7 jours après la dernière visite au cours de laquelle une administration de tréprostinil aura été effectuée

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	10
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Reporting groups

Reporting group title	Treprostinil + NaCl
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Reporting group description: -

Serious adverse events	Treprostinil + NaCl		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 60 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Treprostinil + NaCl		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 60 (20.00%)		
Skin and subcutaneous tissue disorders			
dermabrasion			
subjects affected / exposed	12 / 60 (20.00%)		
occurrences (all)	23		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 May 2015	La modification envisagée est la suivante : <ul style="list-style-type: none">- réaliser une étude ancillaire sur 12 volontaires sains supplémentaires à la concentration de 1mg/ml au lieu de 0.1 mg/ml.- Mise à jour du RCP Remodulin- Modification de la date de fin de l'étude : janvier 2016- Durée de l'étude par sujet (42 jours)- Mise à jour des coordonnées vigilance

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported