# 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 |

### 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 consentem

### 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 |

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 10 |

### Reporting groups

| | |
|---|---|
| Reporting group title | Treprostinil + NaCl |

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 :<br>- réaliser une étude ancillaire sur 12 volontaires sains supplémentaires à la concentration de 1mg/ml au lieu de 0.1 mg/ml.<br>- Mise à jour du RCP Remodulin<br>- Modification de la date de fin de l'étude : janvier 2016<br>- Durée de l'étude par sujet (42 jours)<br>- Mise à jour des coordonnées vigilance |

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported