Clinical trial results:
Study of the intranasal fentanyl tolerance in procedural pain in the elderly, with or without background treatment.

Summary

EudraCT number	2014-003156-31
Trial protocol	FR
Global end of trial date	24 October 2017

Results information

Result version number	v1 (current)
This version publication date	17 June 2022
First version publication date	17 June 2022

Trial information

Trial identification

Sponsor protocol code	38RC14.245

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	CHU de GRENOBLE
Sponsor organisation address	CS 2017, Grenoble, France, 38043
Public contact	Pr GAVAZZI, CHU de GRENOBLE, MCoutard@chu-grenoble.fr
Scientific contact	Pr GAVAZZI, CHU de GRENOBLE, MCoutard@chu-grenoble.fr
Sponsor organisation name	CHU de GRENOBLE
Sponsor organisation address	CS 2017, Grenoble, France, 38043
Public contact	CHU de GRENOBLE, CHU de GRENOBLE, ARCpromoteur@chu-grenoble.fr
Scientific contact	CHU de GRENOBLE, CHU de GRENOBLE, ARCpromoteur@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	06 March 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 October 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the safety of transmucosal fentanyl (Pecfent®) in the procedural pain of the elderly patient.

Protection of trial subjects:

An oversight committee independent of the proponent is foreseen as part of this study.
This committee may propose to the sponsor and the coordinating investigator, the cessation of this research or a modification of the protocol if the safety of the subjects suitable for the study does not seem sufficient.
The Committee will meet at half of the inclusions in the study and in the event of an unexpected serious adverse reaction.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	10 December 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 58
Worldwide total number of subjects	58
EEA total number of subjects	58

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)	0
From 65 to 84 years	11
85 years and over	47

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:
Study will be proposed to all patients with a EVA > 4 during nursing

Period 1

Period 1 title	Evaluation without fentanyl
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:
non applicable

Arms

Arm title	baseline

Arm description: -

Arm type	no product
Investigational medicinal product name	PLACEBO
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Nasal use

Dosage and administration details:
no adminsitration of product

Number of subjects in period 1	baseline
Started	58
Completed	58

Period 2

Period 2 title	Evaluation with fentanyl
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Fentanyl administration
Arm description: -	
Arm type	Active comparator
Investigational medicinal product name	fentanyl
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, suspension
Routes of administration	Intranasal use

Dosage and administration details:

starting with 100µg, with the possibility of increasing dosage over successive procedures according to pain assessments up to 400µg for opioid naïve patients and up to 800µg for others

Number of subjects in period 2	Fentanyl administration
Started	58
Completed	58

Baseline characteristics

End points

End points reporting groups

Reporting group title	baseline
Reporting group description: -	
Reporting group title	Fentanyl administration
Reporting group description: -	
Subject analysis set title	analyse finale
Subject analysis set type	Full analysis

Subject analysis set description:

All quantitative variables are described by their mean, median, minimum, maximum, first and third quartiles. Qualitative parameters are expressed as numbers and percentages

Primary: Primary end point EVA

End point title	Primary end point EVA

End point description:

The effectiveness on pain will be evaluated with a 10 cm EVA that will be offered to the patient. The first six sessions of care, the patient will assess the pain he feels
- 10 minutes before the start of the treatment, just before taking Pecfent® when it is administered.
- during the treatment at 15 minutes compared to t0, after 5 minutes of treatment.
- during the treatment, 30 minutes after t0, after 20 minutes of care.
- A final evaluation will be made at 1 hour from the end of the care

End point type	Primary

End point timeframe:

- 10 minutes before the start of the treatment,
- during the treatment at 15 minutes compared to t0, after 5 minutes of treatment.
- during the treatment, 30 minutes after t0, after 20 minutes of care.
- A final evaluation will be made at 1 hour from

End point values	Fentanyl administration	baseline		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58	58		
Units: cm				
number (not applicable)	58	58		

Statistical analyses

Statistical analysis title	Shapiro-Wilks
Comparison groups	Fentanyl administration v baseline
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.05
Method	Regression, Linear

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AE reporting was during all the study course at each adminsitration and visits

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21

Reporting groups

Reporting group title	Fentanyl Administration

Reporting group description: -

Serious adverse events	Fentanyl Administration		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 58 (6.90%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Respiratory, thoracic and mediastinal disorders			
Cheyne-Stokes respiration			
subjects affected / exposed	1 / 58 (1.72%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Product issues			
Accidental overdose			
subjects affected / exposed	1 / 58 (1.72%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Overdose			
subjects affected / exposed	2 / 58 (3.45%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Fentanyl Administration		
Total subjects affected by non-serious adverse events subjects affected / exposed	16 / 58 (27.59%)		
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	8 / 58 (13.79%) 0		
Vomiting subjects affected / exposed occurrences (all)	8 / 58 (13.79%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 May 2016	This request for a substantial amendment is intended to update the Pecfent® SPC and consequently the relevant paragraphs in the Protocol. In addition, the chapter on vigilance of this study has been updated
28 October 2016	This amendment aims to remove the distribution of the number of patients to be included (30 pressure ulcer treatments / 30 rehabilitation), in order to be able to increase the number of volunteers that can be included in the "mobilization" group without changing the total number of planned inclusions. This substantial amendment is also intended to update the Pecfent® SPC and consequently the relevant paragraphs in the Protocol.
22 February 2017	This amendment aims to add 2 co-investigators: Dr. Mitha and Dr. Zerhouni This substantial amendment also aims to update the Pecfent's® SPC and update the composition of the independent oversight committee.
26 June 2017	This amendment aims to extend the recruitment period of subjects by 6 months which brings the maximum date of last visit of the last patient to 09/12/2017.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported