Clinical trial results:
PROTOCOLE D'ANALGESIE POST OPERATOIRE PAR INFILTRATION CONTINUE DE ROPIVACAINE DANS LES ARTHRODESES DU RACHIS LOMBAIRE

Summary

EudraCT number	2008-004705-34
Trial protocol	FR
Global end of trial date	17 December 2010

Results information

Result version number	v1 (current)
This version publication date	29 June 2022
First version publication date	29 June 2022
Summary attachment (see zip file)	Final Rapport (Résumé du Rapport Final CPPAFSSAPSrenseigne.pdf)

Trial information

Trial identification

Sponsor protocol code	08-CIR-03

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	chu de nice
Sponsor organisation address	DRCI-Hôpital de Cimiez - 4 avenue reine victoria, Nice, France, 06003
Public contact	Direction de la Recherche clinique, DRCI, +33 492034589, caillon.c@chu-nice.fr
Scientific contact	Investigateur , Pr Litrico, +33 492036217 , caillon.c@chu-nice.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	17 December 2010
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 July 2010
Global end of trial reached?	Yes
Global end of trial date	17 December 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Compare the evolution of the postoperative levels of pain until J2, in the scheduled lumbar surgery between 2 groups of patients, one receiving a single bolus of analgesic, one receiving a single bolus of analgesic and an infiltration of Ropivacaine during 48 hours.

Protection of trial subjects:

The patients signed consent

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 December 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	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)	58
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

After we obtained approval from the ethics committee and informed, written consent from patients, patients older than 18 years old , heavier than 50 kg, without psychological disorders, benefiting from of arthrodesis scheduled by a rachis lumbar posterior way were enrolled.

Patients were randomized to one of the two following postoperative analg

Period 1

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

Arms

Arm title	Ropivacaine or serum

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for intravesical solution
Routes of administration	Intramuscular and intravenous use

Dosage and administration details:

200mg of ropivacaïne 0,5 %

Number of subjects in period 1	Ropivacaine or serum
Started	58
Completed	58

Baseline characteristics

Reporting groups

Reporting group title	Inclusion Period

Reporting group description: -

Reporting group values	Inclusion Period	Total	
Number of subjects	58	58	
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)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	58	58	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	25	25	
Male	33	33	

End points

End points reporting groups

Reporting group title	Ropivacaine or serum

Reporting group description: -

Primary: Levels of pain

End point title	Levels of pain[1]

End point description:

End point type	Primary

End point timeframe:

2 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: The statiscal analyses have been specified for this primary end point in the document attached.

End point values	Ropivacaine or serum			
Subject group type	Reporting group			
Number of subjects analysed	58			
Units: NA	58			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

At 2 days

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17

Reporting groups

Reporting group title	Ropivacaine

Reporting group description: -

Serious adverse events	Ropivacaine		
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	Ropivacaine		
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: Any adverse events

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