



Clinical trial results:

Evaluation comparative, en double aveugle, de l'efficacité d'infiltrations locales per et post opératoires de ropivacaïne dans la prise en charge de la douleur après chirurgie hépatique chez l'adulte

Summary

EudraCT number	2007-007968-19
Trial protocol	FR
Global end of trial date	17 February 2014

Results information

Result version number	v1 (current)
This version publication date	26 February 2020
First version publication date	26 February 2020
Summary attachment (see zip file)	DPO (Clinicaltrials.gov.pdf)

Trial information

Trial identification

Sponsor protocol code	ET2007-073
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Centre Léon Bérard
Sponsor organisation address	28 rue Laennec , LYON Cedex 08, France, 69373
Public contact	Dr PERES BACHELOT, Centre Léon Bérard, +33 4 78 78 28 28, DRCIreglementaire@lyon.unicancer.fr
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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 June 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 February 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Evaluer l'efficacité d'infiltrations locales per et post opératoires (sur le site opératoire) de ropivacaïne versus sérum physiologique, sur la consommation de morphine par le patient au cours des 96 heures postopératoires

Protection of trial subjects:

Within the framework of this study, the patients included will be followed according to the recommendations for the management of patients operated on for hepatic metastases : medical follow-up with biological assays, tumor markers.

The patient's postoperative pain will be assessed using a simple verbal scale, and titrated with morphine hydrochloride. A morphine PCA will be put in place at the end of the titration.

No visit or any examination specific to this study is scheduled in addition to the usual follow-up.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 March 2009
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: 85
Worldwide total number of subjects	85
EEA total number of subjects	85

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)	85
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

Participant will be included by the anesthesiologist or the surgeon who, after verifying their eligibility, will have informed them about the study. After a sufficient reflection period, the participant will be invited to give his consent in writing. This form will also be dated and signed by the investigator.

Pre-assignment

Screening details:

No screening

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Experimental Arm

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Infiltration

Dosage and administration details:

- 40 mL of Ropivacaine 3,75 mg/ml in infiltration of the entire operating site at the end of the intervention.
- 768 mL of Ropivacaine 2 mg/ml in infiltration continues at a rate of 8 mL/h for 96 hours.

Arm title	Control Arm
Arm description: -	
Arm type	Physiological serum
Investigational medicinal product name	Physiological serum
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Infiltration

Dosage and administration details:

- 40 mL of Physiological serum of the entire operating site at the end of the intervention.
- Continuous pre-peritoneal infiltration of physiological serum at a flow rate of 8 mL / h, closing of the peritoneum and for 96 h, via one or more multi-perforated catheters and DM COOPDECH Ballonjector®) or an electric syringe .

Number of subjects in period 1	Experimental Arm	Control Arm
Started	42	43
Completed	42	43

Baseline characteristics

Reporting groups

Reporting group title	Experimental Arm
Reporting group description: -	
Reporting group title	Control Arm
Reporting group description: -	

Reporting group values	Experimental Arm	Control Arm	Total
Number of subjects	42	43	85
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	42	43	85
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	11	21	32
Male	31	22	53

Subject analysis sets

Subject analysis set title	Experimental arm
Subject analysis set type	Intention-to-treat
Subject analysis set description: The ITT population is made up of the 85 patients included in the study, including 42 in the Experimental arm (Ropivacaine) and 43 in the Control arm (physiological serum).	
Subject analysis set title	Control arm
Subject analysis set type	Intention-to-treat
Subject analysis set description: The ITT population is made up of the 85 patients included in the study, including 42 in the Experimental arm (Ropivacaine) and 43 in the Control arm (physiological serum).	

Reporting group values	Experimental arm	Control arm	
Number of subjects	42	43	
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)	42	43	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	11	21	
Male	31	22	

End points

End points reporting groups

Reporting group title	Experimental Arm
Reporting group description: -	
Reporting group title	Control Arm
Reporting group description: -	
Subject analysis set title	Experimental arm
Subject analysis set type	Intention-to-treat
Subject analysis set description: The ITT population is made up of the 85 patients included in the study, including 42 in the Experimental arm (Ropivacaine) and 43 in the Control arm (physiological serum).	
Subject analysis set title	Control arm
Subject analysis set type	Intention-to-treat
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Primary: Endpoint analysis

End point title	Endpoint analysis
End point description:	
End point type	Primary
End point timeframe:	
The patient population not assessable for the primary endpoint was made up of patients for whom the total dose of morphine could not be calculated due to at least one missing data (at least one dose of morphine not given). 8 patients were not assessable.	

End point values	Experimental Arm	Control Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	43		
Units: 96h/kg				
median (full range (min-max))	1 (0.1 to 4.0)	1.5 (0.6 to 3.8)		

Statistical analyses

Statistical analysis title	Statistical analysis
Comparison groups	Experimental Arm v Control Arm
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.026
Method	Wilcoxon (Mann-Whitney)

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.

Assessment type	Systematic
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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:	Ropivacaine arm		Control arm
Patient with at least 1 AE	25	23	
Patient with at least one event			
treatment related adverse	6		7
Patient with at least one event grade ≥ 3	14	9	
Patient with at least one event			
related adverse grade ≥ 3	3		1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 August 2009	.modifications of medical devices : - Any multi-perforated catheter with CE marking (instead of systematically using Profolis PaincAth® catheters from Districlass Médical SA) - Continuous infusion pump or an electric syringe with CE marking (instead of systematically using COOPDECH Ballonjector®) .modification of the inclusion balance : the FEVG will now only be performed in the event of a cardiac history and / or abnormal ECG.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported