Clinical trial results:
Does the use of the ropicaine facilitate laparoscopic cholecystectomy in ambulatory surgery?

Summary

EudraCT number	2013-005109-30
Trial protocol	FR
Global end of trial date	05 May 2015

Results information

Result version number	v1 (current)
This version publication date	26 June 2022
First version publication date	26 June 2022

Trial information

Trial identification

Sponsor protocol code	CHD079-13

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02085902
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Centre Hospitalier Départemental Vendée
Sponsor organisation address	Bd Stéphane Moreau, La roche sur yon, France, 85000
Public contact	MARTIN Stéphanie , Centre Hospitalier Départemental Vendée, +33 0251446483, stephanie.martin@chd-vendee.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	07 September 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 May 2015
Global end of trial reached?	Yes
Global end of trial date	05 May 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study is to increase by 24,4 % the number of outpatient laparoscopic cholecystectomy

Protection of trial subjects:

Patient have to sign an informed consent.

Background therapy:

All patients had general anesthesia .
The per-operative anesthesia protocol was as follows:
• _ During induction, propofol, remifentanil and atracurium0.5 mg/kg.
• _ Liquid intake of 1000 ml
• _ Before incision ketamine 0.15 mg/kg
• _ Analgesic 30–45 min before the end of surgery:paracetamol 15 mg/kg, ketoprofen 1 mg/Kg, morphine100 lg/kg, nefopam 20 mg in the absence of contraindications.
Postoperative analgesia was as follows:
• _ paracetamol 1 g 9 4/days
• _ Ketoprofen 100 mg 1 cp 9 2/days
• _ Oxycodone 5 mg every 4–6 h if needed (step 3)
•_ Ondansetron 4 mg if postoperative nausea or vomiting.
If necessary some step 2 medications could be used such as nefopam, tramadol.

Evidence for comparator: -

Actual start date of recruitment	24 March 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: 100
Worldwide total number of subjects	100
EEA total number of subjects	100

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	100
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

First inclusion:24/03/2014
Last inclusion:31/03/2015

124 patients were screened for inclusion
122 patient signed an informed consent
102 patient were randomised but 2 have withdrawn their consent before cholecystectomy (no data collection for these 2 patients)
100 patients were analysed

One Study site : CHD Vendée La Roche sur YON, France

Pre-assignment

Screening details:

124 patients were screened for inclusion

Period 1

Period 1 title	période de traitement (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

Ropivacaine is started during the open surgery (depending on the randomization arm), and then the pain will be collected in a second time by a nurse or a surgeon in a blinded fashion at H2, H6, D1,
The evaluation of the primary endpoint will be done in a blinded fashion by a nurse or a surgeon different from the one who performed the procedure.

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Arms

Are arms mutually exclusive?	Yes
Arm title	Standard anesthesia

Arm description: -

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Standard anesthesia with ropivacaine

Arm description: -

Arm type	Experimental
Investigational medicinal product name	ropivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Gastroenteral use

Dosage and administration details:

150 mg (7,5 mg/ml : 20 ml diluted in 40 mL of saline

Number of subjects in period 1	Standard anesthesia	Standard anesthesia with ropivacaine
Started	50	50
H2	50	50
H6	50	50
J1	50	50
J0 = cholecystectomy	50	50
Completed	50	50

Baseline characteristics

Reporting groups	
Reporting group title	Standard anesthesia
Reporting group description: -	
Reporting group title	Standard anesthesia with ropivacaine
Reporting group description: -	

Reporting group values	Standard anesthesia	Standard anesthesia with ropivacaine	Total
Number of subjects	50	50	100
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)	50	50	100
From 65-84 years	0	0	0
85 years and over	0	0	0
Not recorded	0	0	0
Age continuous			
Age (year)			
Units: years			
arithmetic mean	45.7	49.9	
standard deviation	± 13.4	± 15.3	-
Gender categorical Units: Subjects			
Female	35	34	69
Male	15	16	31
Operative Cholangiography Units: Subjects			
Operative Cholangiography	48	47	95
Not recorded	2	3	5
Temperature Units: °C			
arithmetic mean	36.7	36.9	
standard deviation	± 0.4	± 0.5	-
Cardiac frequency Units: bpm			
arithmetic mean	77	79.4	
standard deviation	± 13.1	± 14.2	-
Systolic arterial pressure Units: mmHg			
arithmetic mean	127.3	127.5	
standard deviation	± 17.8	± 17.1	-

Diastolic arterial pressure Units: mmHg			
arithmetic mean	76.4	76.7	
standard deviation	± 10	± 9.5	-
respiratory frequency Units: /min			
arithmetic mean	18.5	17.3	
standard deviation	± 9.7	± 3.1	-
Lengh of surgery Units: minute			
arithmetic mean	57.2	56.1	
standard deviation	± 16	± 11.7	-

End points

End points reporting groups

Reporting group title	Standard anesthesia
Reporting group description: -	
Reporting group title	Standard anesthesia with ropivacaine
Reporting group description: -	

Primary: Effective hospital discharge of patient

End point title	Effective hospital discharge of patient

End point description:

Six hours after surgery, the patient was evaluated to authorize home discharge. For this evaluation, the Chung score for discharge was used . Discharge was authorized with a score equal to or above 9. However, depending on the situation, it is possible that a patient with a Chung score higher than 9 may require prolonged hospitalization, which is why :
Will be considered "successful": all patients for whom a discharge decision has been made at H6 with an effective discharge, whatever the Chung score obtained.
Will be considered a "failure": all patients requiring an extension of their stay in a traditional digestive surgery hospital (or other service) after H6, whatever the Chung score obtained.

End point type	Primary

End point timeframe:

H6

End point values	Standard anesthesia	Standard anesthesia with ropivacaine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: number of patient				
Effective hospital discharge	49	49		

Statistical analyses

Statistical analysis title	Effective hospital discharge of patient
Comparison groups	Standard anesthesia v Standard anesthesia with ropivacaine
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1
Method	Chi-squared

Primary: Chung Score < 9

End point title	Chung Score < 9

End point description:

End point type	Primary

End point timeframe:

H6

End point values	Standard anesthesia	Standard anesthesia with ropivacaine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Number of patient				
Chun Score <9	2	2		

Statistical analyses

Statistical analysis title	Chung score
Comparison groups	Standard anesthesia v Standard anesthesia with ropivacaine
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1
Method	Chi-squared

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From randomisation (intervention) until end of participation of patient (J1)	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19

Reporting groups	
Reporting group title	Standard Anesthesia
Reporting group description: -	
Reporting group title	Standard anesthesia with ropivacine
Reporting group description: -	

Serious adverse events	Standard Anesthesia	Standard anesthesia with ropivacine	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Standard Anesthesia	Standard anesthesia with ropivacine	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 50 (52.00%)	26 / 50 (52.00%)	
General disorders and administration site conditions			
Pain			
subjects affected / exposed	9 / 50 (18.00%)	8 / 50 (16.00%)	
occurrences (all)	9	9	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	13 / 50 (26.00%)	17 / 50 (34.00%)	
occurrences (all)	13	17	
Nausea			
subjects affected / exposed	6 / 50 (12.00%)	5 / 50 (10.00%)	
occurrences (all)	6	5	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 May 2014	The following inclusion criteria was deleted : patient living at less than 50 Km from CHd Vendee
03 February 2015	Increase of study duration Increase of number of patient to be included (from 100 to 120) because of the number of screen failure and in order to reach 90 analyzable patients

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported