



Clinical trial results: analgesia with continuous IV-infusion of lidocain during the perioperative period in patients undergo laparoscopic sterilization.

Summary

EudraCT number	2011-001315-31
Trial protocol	BE
Global end of trial date	29 May 2015

Results information

Result version number	v1 (current)
This version publication date	01 January 2020
First version publication date	01 January 2020

Trial information

Trial identification

Sponsor protocol code	GD032011
-----------------------	----------

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University Hospitals Leuven
Sponsor organisation address	herestraat, leuven, Belgium, 3001
Public contact	Anesthesia Research, University Hospitals Leuven, 32 16344620, christel.huygens@uzleuven.be
Scientific contact	Anesthesia Research, University Hospitals Leuven, 32 16344620, christel.huygens@uzleuven.be

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	09 September 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 May 2015
Global end of trial reached?	Yes
Global end of trial date	29 May 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Is the perioperative IV administration of lidocaine an effective treatment to reduce postoperative pain after surgical sterilization.

Protection of trial subjects:

The interventional treatment was administered to patients with standard hemodynamic monitoring in the setting of a fully equipped operation theatre. This enabled immediate detection and treatment of potential adverse events. Administration of study drugs was to be immediately stopped in case that the study participant showed signs of systemic toxicity (metallic taste, tinnitus, headache, seizure activity and ECG irregularities). Also after leaving the operation room, all patients were closely monitored for the occurrence of eventual (severe) adverse events.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 September 2011
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	Belgium: 80
Worldwide total number of subjects	80
EEA total number of subjects	80

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)	80
From 65 to 84 years	0

85 years and over	0
-------------------	---

Subject disposition

Recruitment

Recruitment details:

116 patients were assessed for eligibility, 80 patients were enrolled and randomized between November 2011 and may 2015

Pre-assignment

Screening details:

80 women scheduled for laparoscopic sterilisation were included in this prospective, double-blind, randomised, placebo-controlled clinical trial.

one patient was excluded from analysis because change of operation

Pre-assignment period milestones

Number of subjects started	80
Number of subjects completed	80

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	lidocaine

Arm description:

intravenously lidocaine

Arm type	Experimental
Investigational medicinal product name	lidocaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous bolus use , Intravenous use

Dosage and administration details:

Patients in the L-group were given an intravenous (IV) bolus injection of lidocaine 1.5 mg.kg⁻¹ at induction of anesthesia followed by a continuous infusion of 1.5 mg.kg⁻¹.h⁻¹ which was continued until 30min after arrival at the PACU.

Arm title	placebo group
------------------	---------------

Arm description:

placebo

Arm type	Experimental
Investigational medicinal product name	saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous drip use , Intravenous bolus use

Dosage and administration details:

Patients in the placebo-group were given an intravenous (IV) bolus injection of saline at induction of anesthesia followed by a continuous infusion of saline which was continued until 30min after arrival at the PACU. Patients in the P-group were given equal volumes of saline.

Number of subjects in period 1	lidocaine	placebo group
Started	40	40
Completed	40	40

Baseline characteristics

Reporting groups

Reporting group title	lidocaine
Reporting group description: intravenously lidocaine	
Reporting group title	placebo group
Reporting group description: placebo	

Reporting group values	lidocaine	placebo group	Total
Number of subjects	40	40	80
Age categorical			
lidocaine: n=39 (19;47) years			
placebo n=40 (27;46)			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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 65-84 years			0
85 years and over			0
Age continuous			
Units: years			
median	37	40	
inter-quartile range (Q1-Q3)	19 to 47	27 to 46	-
Gender categorical			
Units: Subjects			
Female	40	40	80
Male	0	0	0

End points

End points reporting groups

Reporting group title	lidocaine
Reporting group description:	
intravenously lidocaine	
Reporting group title	placebo group
Reporting group description:	
placebo	
Subject analysis set title	a 2-sided test for the detection of differences between propor
Subject analysis set type	Per protocol
Subject analysis set description:	
lidocaine:40	
placebo:40	

Primary: proportion of patients with a NRS greater than 3

End point title	proportion of patients with a NRS greater than 3
End point description:	
proportion of patients with NRS greater than 3	
End point type	Primary
End point timeframe:	
30 min after arrival PACU	

End point values	lidocaine	placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	40		
Units: nuber	40	40		

Statistical analyses

Statistical analysis title	2-sided test for the detection of differences betw
Comparison groups	lidocaine v placebo group
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)
Confidence interval	
level	90 %

Adverse events

Adverse events information

Timeframe for reporting adverse events:

from enrollment until discharge of the patient

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	23
--------------------	----

Reporting groups

Reporting group title	lidocaine group
-----------------------	-----------------

Reporting group description: -

Serious adverse events	lidocaine group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 40 (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	lidocaine group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 40 (2.50%)		
Renal and urinary disorders			
Urinary retention postoperative			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences (all)	1		

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