Clinical trial results:
Pharmacokinetic study of the opioid ketobemidone in neonates after an intravenous administration

Summary

EudraCT number	2008-008012-98
Trial protocol	SE
Global end of trial date	25 March 2012

Results information

Result version number	v1 (current)
This version publication date	12 February 2020
First version publication date	12 February 2020
Summary attachment (see zip file)	Pharmacokinetics after a single dose of the opioid ketobemidone in neonates (KetobemidoneNeonates2012LUNDEBERG_et_al-2012-Acta_Anaesthesiologica_Scandinavica.pdf)

Trial information

Trial identification

Sponsor protocol code	sl2008-1

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Stockholms Läns Landsting
Sponsor organisation address	Karolinska University Hospital, Stockholm, Sweden, 17176
Public contact	Stefan Lundeberg, Karolinska University Hospital, +46 851777189, stefan.lundeberg@sll.se
Scientific contact	Stefan Lundeberg, Karolinska University Hospital, +46 851777189, stefan.lundeberg@sll.se

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	29 April 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 April 2011
Global end of trial reached?	Yes
Global end of trial date	25 March 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Determination of pharmacokinetic parameters of ketobemidone after an intravenous injection

Protection of trial subjects:

Bloodsamples taken from an indwelling catheter which was used for the postoperative care.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 August 2010
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	Sweden: 15
Worldwide total number of subjects	15
EEA total number of subjects	15

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	15
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	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Neonates scheduled for elective surgery.Consent given by care givers

Pre-assignment

Screening details:

16 patients were screened. In one case no consent was given.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Single arm

Arm description:

Patients recruited and after consent given the drug ketobemidone during surgery. Blood samples were taken för concentration analysis of ketobemidone.

Arm type	Experimental
Investigational medicinal product name	Ketobemidone hydrochloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

0.05 mg/kg of ketobemidone, intravenous injektion during anesthesia

Number of subjects in period 1	Single arm
Started	15
Completed	15

Baseline characteristics

Reporting groups

Reporting group title	Overall trial

Reporting group description:

Newborns receiving ketobemidone iv as a single dose

Reporting group values	Overall trial	Total	
Number of subjects	15	15	
Age categorical			
Newborns			
Units: Subjects			
Newborns	15	15	
Gender categorical Units: Subjects			
Female Male	8 7	8 7	
Age			
Newborns			
Units: Subjects			
Newborns	15	15	

Subject analysis sets

Subject analysis set title	Pharmacokinetics
Subject analysis set type	Per protocol

Subject analysis set description:

Pharmacokinetics after a single dose of ketobemidone in neonates. Plasma concentration

Reporting group values	Pharmacokinetics		
Number of subjects	15		
Age categorical			
Newborns			
Units: Subjects			
Newborns	15		
Gender categorical Units: Subjects			
Female Male			
Age			
Newborns			
Units: Subjects			
Newborns	15		

End points

End points reporting groups

Reporting group title	Single arm

Reporting group description:

Patients recruited and after consent given the drug ketobemidone during surgery. Blood samples were taken för concentration analysis of ketobemidone.

Subject analysis set title	Pharmacokinetics
Subject analysis set type	Per protocol

Subject analysis set description:

Pharmacokinetics after a single dose of ketobemidone in neonates. Plasma concentration

Primary: Pharmacokinetic

End point title	Pharmacokinetic

End point description:

End point type	Primary

End point timeframe:

When all blood samples had been analysed and pharmacokinetic parameters had been calculated

End point values	Single arm	Pharmacokinetics		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	15	15		
Units: ng/ml				
number (not applicable)	15	15		

Statistical analyses

Statistical analysis title	Descriptive

Statistical analysis description:

Measure of plasma concentration and pharmacokinetic parameters.

Comparison groups	Single arm v Pharmacokinetics
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	< 0.05 [2]
Method	Wilcoxon (Mann-Whitney)

Notes:

[1] - Concentration in plasma, calculations median and range values for different parameters

[2] - not applicable

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Until 48 hours after last blood sample

Assessment type	Systematic

Dictionary used

Dictionary name	Local protocol
Dictionary version	1

Reporting groups

Reporting group title	Ketobemidone neonates

Reporting group description: -

Serious adverse events	Ketobemidone neonates		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Ketobemidone neonates		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 15 (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: In this small group of patients receiving the opioid ketobemidone we did not record any non-serious advents. Ketobemidone is used routinely as an analgesic in the postoperative period.

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

None

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/22834454