Clinical trial results:
Stressi-indeksi (SSI) sevofluraani-alfentaniilianestesiassa

Summary

EudraCT number	2006-003765-14
Trial protocol	FI
Global end of trial date	04 May 2007

Results information

Result version number	v1 (current)
This version publication date	02 March 2019
First version publication date	02 March 2019
Summary attachment (see zip file)	Summary Stressi-indeksi (SSI) sevofluraani-alfentaniilianestesiassa (Loppuraportti.doc)

Trial information

Trial identification

Sponsor protocol code	SSIVALTA0706

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	GE Healthcare Finland Oy
Sponsor organisation address	Kuortaneenkatu 2, Helsinki, Finland,
Public contact	Kimmo Uutela, ALFESEVOSSI01.txt, +358 405732817, kimmo.uutela@ge.com
Scientific contact	Kimmo Uutela, ALFESEVOSSI01.txt, +358 405732817, kimmo.uutela@ge.com

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	23 August 2007
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 November 2006
Global end of trial reached?	Yes
Global end of trial date	04 May 2007
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Tutkia stressi-indeksin herkkyyttä analgeettiselle lääkitykselle (alfentaniili)

Protection of trial subjects:

Normal surgery procedure

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 September 2006
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	Finland: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

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)	33
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Inclusion: Age 18-80, ASAI-III, general anesthesia
Exclusion: Allergy to used drugs

Period 1

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

Blinding implementation details:

Surgical drug variation blinded from patient but not from caregiver

Arms

Are arms mutually exclusive?	Yes
Arm title	Alfentanil change

Arm description: -

Arm type	Drug variation
Investigational medicinal product name	SEVOFLURANE
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Effect-site concentration control

Arm title	Sevoflurane change

Arm description:

Sevoflurane change

Arm type	Drug change

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Alfentanil change	Sevoflurane change
Started	20	20
Completed	20	20

Baseline characteristics

Reporting groups	
Reporting group title	Alfentanil change
Reporting group description: -	
Reporting group title	Sevoflurane change
Reporting group description: Sevoflurane change	

Reporting group values	Alfentanil change	Sevoflurane change	Total
Number of subjects	20	20	40
Age categorical			
Age			
Units: Subjects			
Adults (18-64 years)	16	17	33
From 65-84 years	4	3	7
Gender categorical Units: Subjects			
Female	20	20	40

End points

End points reporting groups

Reporting group title	Alfentanil change
Reporting group description: -	
Reporting group title	Sevoflurane change
Reporting group description: Sevoflurane change	

Primary: SSi Change

End point title	SSi Change[1]
End point description:	
End point type	Primary
End point timeframe: During surgery	

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: Measuring change within group, not comparing between

End point values	Alfentanil change	Sevoflurane change		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	19		
Units: SSI				
median (standard deviation)	-8 (± 14)	-9.6 (± 15)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: End of study	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	None
Dictionary version	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: No serious 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