Clinical trial results:
A psychomotor recuperation study after deep sedation for colonoscopy between target controlled and manual titration of propofol.

Summary

EudraCT number	2014-005215-16
Trial protocol	BE
Global end of trial date	21 February 2020

Results information

Result version number	v1 (current)
This version publication date	29 July 2021
First version publication date	29 July 2021

Trial information

Trial identification

Sponsor protocol code	CHUB-MentalRecup001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02314559
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	CHU Brugmann
Sponsor organisation address	4 Place A. Van Gehuchten, Brussels, Belgium, 1020
Public contact	Anesthesiology Service , CHU Brugmann, 32 024773996, Philippe.VANDERLINDEN@chu-brugmann.be
Scientific contact	Anesthesiology Service , CHU Brugmann, 32 024773996, Philippe.VANDERLINDEN@chu-brugmann.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	21 February 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 February 2020
Global end of trial reached?	Yes
Global end of trial date	21 February 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Our aim is to evaluate efficacy and recovery after manual titration and target controlled infusion (TCI) of propofol, during colonoscopy, for ambulatory patients. We will evaluate both groups during and after colonoscopy for adverse events, quality of sedation and recovery of psychomotor function.

Protection of trial subjects:

The study followed the standard of care regarding pain mangement.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 February 2015
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: 154
Worldwide total number of subjects	154
EEA total number of subjects	154

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)	109
From 65 to 84 years	45
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

184 patients were assessed for eligibility. 164 patients were randomized. 10 patients were excluded (withdrew consent, modified procedures, cancelled procedures and technical problems, hospitalizations). 154 patients were analyzed.

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, Assessor, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Bolus group

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Propofol 10mg/ml (Diprivan)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

10mg/ml, intravenous administration.

Arm title	TCI Group

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Propofol 10mg/ml (Diprivan)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

10mg/ml, intravenous administration.

Number of subjects in period 1	Bolus group	TCI Group
Started	79	75
Completed	79	75

Baseline characteristics

Reporting groups	
Reporting group title	Bolus group
Reporting group description: -	
Reporting group title	TCI Group
Reporting group description: -	

Reporting group values	Bolus group	TCI Group	Total
Number of subjects	79	75	154
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)	53	56	109
From 65-84 years	26	19	45
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	47	38	85
Male	32	37	69

End points

End points reporting groups	
Reporting group title	Bolus group
Reporting group description: -	
Reporting group title	TCI Group
Reporting group description: -	

Primary: Differences in 'fit for discharge' time	
End point title	Differences in 'fit for discharge' time
End point description:	
End point type	Primary
End point timeframe:	
up to 60 minutes after colonoscopy cessation	

End point values	Bolus group	TCI Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	79	75		
Units: minutes	20	20		

Statistical analyses

Statistical analysis title	Mann-Whitney UTest
Comparison groups	Bolus group v TCI Group
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Overall trial	
Assessment type	Systematic
Dictionary used	
Dictionary name	Clinical Practice
Dictionary version	N/A
Reporting groups	
Reporting group title	Bolus group
Reporting group description: -	
Reporting group title	TCI Group
Reporting group description: -	

Serious adverse events	Bolus group	TCI Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 79 (0.00%)	0 / 75 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	Bolus group	TCI Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	39 / 79 (49.37%)	38 / 75 (50.67%)	
Cardiac disorders			
Hypotension (intraoperative)	Additional description: Intraoperative hypotension		
subjects affected / exposed	39 / 79 (49.37%)	38 / 75 (50.67%)	
occurrences (all)	1	1	
Hypotension (post-operative)	Additional description: Post-operative hypotension		
subjects affected / exposed	17 / 79 (21.52%)	21 / 75 (28.00%)	
occurrences (all)	1	1	
Respiratory, thoracic and mediastinal disorders			
Upper airway obstruction			
subjects affected / exposed	5 / 79 (6.33%)	4 / 75 (5.33%)	
occurrences (all)	1	1	

Oxygen saturation decreased (intraoperative)	Additional description: Intraoperative desaturation		
subjects affected / exposed	1 / 79 (1.27%)	1 / 75 (1.33%)	
occurrences (all)	1	1	
Oxygen saturation decreased (postoperative)	Additional description: Postoperative period		
subjects affected / exposed	0 / 79 (0.00%)	1 / 75 (1.33%)	
occurrences (all)	1	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 April 2016	Change of principal investigator and increase of trial duration
29 May 2017	Increase of trial duration
24 April 2018	Increase of trial duration
27 August 2018	Principal investigator change and increase of trial duration

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported