

**Clinical trial results:  
Patient Satisfaction of Propofol versus Midazolam and Fentanyl  
Sedation during Colonoscopy in Inflammatory Bowel Disease  
Summary**

EudraCT number	2013-002428-17
Trial protocol	DK
Global end of trial date	30 April 2020

**Results information**

Result version number	v1 (current)
This version publication date	17 March 2021
First version publication date	17 March 2021
Summary attachment (see zip file)	Full data set (JeppesDATA.xlsx)

**Trial information****Trial identification**

Sponsor protocol code	2013052044
-----------------------	------------

**Additional study identifiers**

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01934088
WHO universal trial number (UTN)	-

Notes:

**Sponsors**

Sponsor organisation name	Herlev Hospital
Sponsor organisation address	Borgmester Ib Juuls vej 1, Herlev, Denmark, 2730
Public contact	Jeppe Thue Jensen, Gastroenheden D, Herlev Hospital, 0045 26136032, jeppe.thue.jensen.01@regionh.dk
Scientific contact	Jeppe Thue Jensen, Gastroenheden D, Herlev Hospital, 0045 26136032, jeppe.thue.jensen.01@regionh.dk

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	30 April 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 April 2020
Global end of trial reached?	Yes
Global end of trial date	30 April 2020
Was the trial ended prematurely?	No

Notes:

---

**General information about the trial**

---

Main objective of the trial:

To study if patients with inflammatory bowel disease prefer sedation with propofol or midazolam/fentanyl for their colonoscopy, and if the sedation of choice can increase adherence to treatment program

Protection of trial subjects:

Trial subjects were randomized to one of two possible standard treatments available in our department. The treatments were unmodified.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2013
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	Denmark: 130
Worldwide total number of subjects	130
EEA total number of subjects	130

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)	110
From 65 to 84 years	20
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Patients included were  $\geq 18$  years of age and were scheduled for colonoscopy as part of our standard of care for IBD, or as part of diagnostic workup in patients suspected for having IBD.

320 patients were screened. 130 patients were included. Of the 190 patients declining inclusion, 133 opted out due to specific sedation preferences.

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Propofol sedation

Arm description:

Deep sedation with propofol administered by a designated nurse supervised by the endoscopist.

Arm type	Experimental
Investigational medicinal product name	Propofol "B. Braun"
Investigational medicinal product code	N01AX10
Other name	
Pharmaceutical forms	Emulsion for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Propofol 10 mg/ml Emulsion.

Induction with bolus 20-80 mg (100 minus patient age) and subsequent induction bolus corresponding to half the initial dose 10-40 mg.

Sedation maintenance with bolus 10-20 mg every 1-2 minute, if the patients shows signs of being awake, or is otherwise respiratory and circulatory stable.

<b>Arm title</b>	Midazolam/fentanyl sedation
------------------	-----------------------------

Arm description:

Moderate sedation was administered by a dedicated nurse supervised by the endoscopist. Initial Fentanyl dose of 0.05 mg ( $\leq 60$  years of age) and 0.025 mg ( $\geq 61$  years of age) was administered at least five minutes prior to procedure. Induction dose with Midazolam was 1-5 mg and 0.5-2 mg for maintenance when necessary.

Arm type	Active comparator
Investigational medicinal product name	Fentanyl "B. Braun"
Investigational medicinal product code	N05CD08, N01AH01
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Induction dose with Midazolam was 1-5 mg and 0.5-2 mg for maintenance when necessary.

Investigational medicinal product name	Fentanyl "B. Braun"
Investigational medicinal product code	N01AH01
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intraventricular use

---

Dosage and administration details:

Sedation was administered by a dedicated nurse supervised by the endoscopist according to local protocol.12 Initial Fentanyl dose of 0.05 mg ( $\leq 60$  years of age) and 0.025 mg ( $\geq 61$  years of age) was administered at least five minutes prior to procedure.

<b>Number of subjects in period 1</b>	Propofol sedation	Midazolam/fentanyl sedation
Started	63	67
Completed	62	64
Not completed	1	3
Lost to follow-up	-	1
Protocol deviation	1	2

## Baseline characteristics

### Reporting groups

Reporting group title	Propofol sedation
-----------------------	-------------------

Reporting group description:

Deep sedation with propofol administered by a designated nurse supervised by the endoscopist.

Reporting group title	Midazolam/fentanyl sedation
-----------------------	-----------------------------

Reporting group description:

Moderate sedation was administered by a dedicated nurse supervised by the endoscopist. Initial Fentanyl dose of 0.05 mg ( $\leq 60$  years of age) and 0.025 mg ( $\geq 61$  years of age) was administered at least five minutes prior to procedure. Induction dose with Midazolam was 1-5 mg and 0.5-2 mg for maintenance when necessary.

Reporting group values	Propofol sedation	Midazolam/fentanyl sedation	Total
Number of subjects	63	67	130
Age categorical			
Units: Subjects			
Age = or > 18 years	63	67	130
Gender categorical			
Units: Subjects			
Female	26	38	64
Male	37	29	66

### Subject analysis sets

Subject analysis set title	Propofol sedation
----------------------------	-------------------

Subject analysis set type	Intention-to-treat
---------------------------	--------------------

Subject analysis set description:

63 patients. Age at study, mean years (SD) 41.9 (13.3). ASA class, mean (SD) 1.38 (0.49); BMI, mean kg/m<sup>2</sup> (SD) 24.8 (4.0); Sedative drug mg, mean (SD) 342 (139); Sedation time minutes, mean (SD) 29.9 (11.5); Sleep score 1-5 during intervention, mean (SD) 1=awake, 5=asleep: 4.71 (0.72)

Indication for colonoscopy, no. (%) Diagnostic 19 (30); Evaluation of disease activity at suspected flare 25 (40); Evaluation of disease activity during remission 9 (14); Surveillance for cancer 10 (16).

Subject analysis set title	Midazolam/fentanyl sedation
----------------------------	-----------------------------

Subject analysis set type	Intention-to-treat
---------------------------	--------------------

Subject analysis set description:

67 patients. Age at study, mean years (SD) 41.2 (14.0); ASA class, mean (SD) 1.38 (0.49); BMI, mean kg/m<sup>2</sup> (SD) 24.4 (3.7); Sedative drug mg (Midazolam/Fentanyl), mean (SD) 2.4 (0.5) / 0.06 (0.02); Sedation time minutes, mean (SD) 29.1 (13.6); Sleep score 1-5 during intervention, mean (SD) 1=awake, 5=asleep: 1.31 (0.74).

Indication for colonoscopy, no. (%): Diagnostic 18 (27); Evaluation of disease activity at suspected flare 24 (36); Evaluation of disease activity during remission 18 (27); Surveillance for cancer 7 (10)

Reporting group values	Propofol sedation	Midazolam/fentanyl sedation	
Number of subjects	63	67	

Age categorical			
Units: Subjects			
Age = or > 18 years	63	67	
Gender categorical			
Units: Subjects			
Female	26	38	
Male	37	29	

---

## End points

### End points reporting groups

Reporting group title	Propofol sedation
-----------------------	-------------------

Reporting group description:

Deep sedation with propofol administered by a designated nurse supervised by the endoscopist.

Reporting group title	Midazolam/fentanyl sedation
-----------------------	-----------------------------

Reporting group description:

Moderate sedation was administered by a dedicated nurse supervised by the endoscopist. Initial Fentanyl dose of 0.05 mg ( $\leq 60$  years of age) and 0.025 mg ( $\geq 61$  years of age) was administered at least five minutes prior to procedure. Induction dose with Midazolam was 1-5 mg and 0.5-2 mg for maintenance when necessary.

Subject analysis set title	Propofol sedation
----------------------------	-------------------

Subject analysis set type	Intention-to-treat
---------------------------	--------------------

Subject analysis set description:

63 patients. Age at study, mean years (SD) 41.9 (13.3). ASA class, mean (SD) 1.38 (0.49); BMI, mean kg/m<sup>2</sup> (SD) 24.8 (4.0); Sedative drug mg, mean (SD) 342 (139); Sedation time minutes, mean (SD) 29.9 (11.5); Sleep score 1-5 during intervention, mean (SD) 1=awake, 5=asleep: 4.71 (0.72)

Indication for colonoscopy, no. (%) Diagnostic 19 (30); Evaluation of disease activity at suspected flare 25 (40); Evaluation of disease activity during remission 9 (14); Surveillance for cancer 10 (16).

Subject analysis set title	Midazolam/fentanyl sedation
----------------------------	-----------------------------

Subject analysis set type	Intention-to-treat
---------------------------	--------------------

Subject analysis set description:

67 patients. Age at study, mean years (SD) 41.2 (14.0); ASA class, mean (SD) 1.38 (0.49); BMI, mean kg/m<sup>2</sup> (SD) 24.4 (3.7); Sedative drug mg (Midazolam/Fentanyl), mean (SD) 2.4 (0.5) / 0.06 (0.02); Sedation time minutes, mean (SD) 29.1 (13.6); Sleep score 1-5 during intervention, mean (SD) 1=awake, 5=asleep: 1.31 (0.74).

Indication for colonoscopy, no. (%): Diagnostic 18 (27); Evaluation of disease activity at suspected flare 24 (36); Evaluation of disease activity during remission 18 (27); Surveillance for cancer 7 (10)

### Primary: Patient satisfaction with sedation

End point title	Patient satisfaction with sedation
-----------------	------------------------------------

End point description:

The satisfaction questionnaire consists 13 items. Each item can be scored from 1-5, with 5 representing a better experience with the sedation.

End point type	Primary
----------------	---------

End point timeframe:

Satisfaction questionnaire is completed before discharge from the recovery area.

End point values	Propofol sedation	Midazolam/fentanyl sedation	Propofol sedation	Midazolam/fentanyl sedation
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	62	64	62	64
Units: 13-65				
number (not applicable)	62	64	62	64

<b>Attachments (see zip file)</b>	Table 1/tabel 1.docx
-----------------------------------	----------------------

### Statistical analyses

<b>Statistical analysis title</b>	One-Way Analysis of Variance
Statistical analysis description:	
Comparison of satisfaction scores	
Comparison groups	Midazolam/fentanyl sedation v Propofol sedation
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	ANOVA
Parameter estimate	Mean difference (final values)
Variability estimate	Standard deviation

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

During the procedure and within 1 hour of discharge

Adverse event reporting additional description:

Apnea with bag valve ventilation: 1 patient. Hypoxia (< 92% saturation): 6 patients. Hypotension: 7 patients

Assessment type	Non-systematic
-----------------	----------------

### Dictionary used

Dictionary name	SNOMED CT
-----------------	-----------

Dictionary version	1
--------------------	---

### Reporting groups

Reporting group title	Propofol sedation
-----------------------	-------------------

Reporting group description:

Deep sedation with propofol administered by a designated nurse supervised by the endoscopist.

Reporting group title	Midazolam/fentanyl sedation
-----------------------	-----------------------------

Reporting group description:

Moderate sedation was administered by a dedicated nurse supervised by the endoscopist. Initial Fentanyl dose of 0.05 mg ( $\leq 60$  years of age) and 0.025 mg ( $\geq 61$  years of age) was administered at least five minutes prior to procedure. Induction dose with Midazolam was 1-5 mg and 0.5-2 mg for maintenance when necessary.

Serious adverse events	Propofol sedation	Midazolam/fentanyl sedation	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 63 (0.00%)	1 / 67 (1.49%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Investigations			
Apnoea	Additional description: Midazolam and fentanyl induced apnoea with hypoxia (85% SAT) needing short ventilation with facemask.		
alternative assessment type: Systematic			
subjects affected / exposed	0 / 63 (0.00%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Propofol sedation	Midazolam/fentanyl sedation	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 63 (6.35%)	8 / 67 (11.94%)	

Cardiac disorders Hypotension alternative assessment type: Systematic subjects affected / exposed occurrences (all)	4 / 63 (6.35%) 4	3 / 67 (4.48%) 3	
Respiratory, thoracic and mediastinal disorders Hypoxia alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 63 (0.00%) 0	6 / 67 (8.96%) 6	
Apnoea alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 63 (0.00%) 0	1 / 67 (1.49%) 0	
Additional description: apnoea needing face mask ventilation			

## 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.

Small sample size. Large proportion of screened patients excluded due to specific sedation preferences. Lack of a properly validated satisfaction questionnaire.
---

Notes: