Clinical trial results:
The role of routinely given hyoscine-N- butylbromide in colonoscopy: a double-blind, randomized, placebo-controlled, clinical trial.

Summary

EudraCT number	2011-002408-34
Trial protocol	FI
Global end of trial date	23 October 2014

Results information

Result version number	v1 (current)
This version publication date	01 June 2021
First version publication date	01 June 2021
Summary attachment (see zip file)	HBB study (00365521.2015.1083611.pdf)

Trial information

Trial identification

Sponsor protocol code	Nosponsor

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	No sponsor
Sponsor organisation address	No sponsor, No sponsor, Finland,
Public contact	Laakso Hospital, Matti Ristikankare, +358 503279448, matti.ristikankare@kolumbus.fi
Scientific contact	Laakso Hospital, Matti Ristikankare, +358 503279448, matti.ristikankare@kolumbus.fi

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	01 April 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 March 2014
Global end of trial reached?	Yes
Global end of trial date	23 October 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To find out if the routine use of hyoscine-N- butylbromide is beneficial in colonoscopy.

Protection of trial subjects:

Normal precautions of the colonoscopic procedure. Patients with severe comorbidities or with any medications with potential interactions with hyoscine-N- butylbromide were excluded . Patients were monitored with a pulse oximetry.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2012
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: 150
Worldwide total number of subjects	150
EEA total number of subjects	150

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)	92
From 65 to 84 years	58
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

218 outpatients scheduled for diagnostic colonoscopy fulfilling the eligibility criteria on the basis of the referral were recruited.

Pre-assignment

Screening details:

The eligibility criteria included age between 45 and 75 years, ability to complete a questionnaire, and no history of intolerance to HBB. Patients on anticholinergic medication including tricyclic antidepressants and selective serotonin reuptake inhibitors or with a history of colonic resection, serious comorbidity

Period 1

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

Blinding implementation details:

The patients were randomized in blocks of six by opening a sealed envelope to receive either HBB (HBB group) or saline (placebo group) i.v. The envelopes had been coded and sealed by a person not attending the trial in any other way. An injection of 10 mg (0,5 ml) HBB or an equivalent volume of saline was administered were administered and the heart rate monitored by a nurse not attending the colonoscopic procedure.

Arms

Are arms mutually exclusive?	Yes
Arm title	HBB Buscopan

Arm description:

Patients receiving hyoscine-N- butylbromide

Arm type	Active comparator
Investigational medicinal product name	hyoscine-N- butylbromide Buscopan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

An injection of 10 mg (0,5 ml) HBB or an equivalent volume of saline was administered over 30- 60 seconds three minutes before the introduction of the colonoscope. A supplemental dose of 10 mg HBB or saline was delivered when the tip of the colonoscope reached the cecum.

Arm title	Placebo

Arm description:

The patients receiving placebo.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	Saline
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

An injection of 10 mg (0,5 ml) HBB or an equivalent volume of saline was administered over 30- 60 seconds three minutes before the introduction of the colonoscope. A supplemental dose of 10 mg HBB or saline was delivered when the tip of the colonoscope reached the cecum.

Number of subjects in period 1	HBB Buscopan	Placebo
Started	75	75
Completed	75	75

Baseline characteristics

Reporting groups	
Reporting group title	HBB Buscopan
Reporting group description:	
Patients receiving hyoscine-N- butylbromide	
Reporting group title	Placebo
Reporting group description:	
The patients receiving placebo.	

Reporting group values	HBB Buscopan	Placebo	Total
Number of subjects	75	75	150
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)	43	48	91
From 65-84 years	32	27	59
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	38	45	83
Male	37	30	67

End points

End points reporting groups

Reporting group title	HBB Buscopan
Reporting group description:	
Patients receiving hyoscine-N- butylbromide	
Reporting group title	Placebo
Reporting group description:	
The patients receiving placebo.	

Primary: Patient tolerance

End point title	Patient tolerance
End point description:	
Patient tolerance was the primary endpoint. Assuming that a difference of 15 mm in VAS evaluation is clinically relevant , the sample size was calculated to provide 95% power for detecting a difference between two groups at a 0.05 significance level.	
End point type	Primary
End point timeframe:	
After the examination.	

End point values	HBB Buscopan	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	75	75		
Units: MM				
number (not applicable)	74	75		

Attachments (see zip file)	Figure report.docx

Statistical analyses

Statistical analysis title	Patient tolerance
Statistical analysis description:	
After testing normality of distribution the continuous variables were compared with independent samples Mann Whitney U test or T test, when appropriate. The level of statistical significance was defined as $p < 0.05$. The results are given as mean + SEM.	
Comparison groups	HBB Buscopan v Placebo
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
No adverse events.	
Adverse event reporting additional description:	
No adverse events.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	20

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

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: tachycardia was not considered an advere event,

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