



## Clinical trial results:

**Effects of postoperative palonosetron in ambulatory patients identified with high risk for postdischarge nausea and vomiting (PDNV) – a randomized controlled trial with comparison to placebo.**

### Summary

EudraCT number	2015-003956-32
Trial protocol	SE
Global end of trial date	10 April 2020

### Results information

Result version number	v1 (current)
This version publication date	15 June 2023
First version publication date	15 June 2023
Summary attachment (see zip file)	Delayed results (Report of delayed results.pdf)

### Trial information

#### Trial identification

Sponsor protocol code	POSTPAL
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#### Additional study identifiers

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

Notes:

#### Sponsors

Sponsor organisation name	Umeå University
Sponsor organisation address	x, Umeå, Sweden,
Public contact	Jakob Wallden, Umeå University, jakob.wallden@umu.se
Scientific contact	Jakob Wallden, Umeå University, +46 703644392, jakob.wallden@umu.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	15 November 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 April 2020
Global end of trial reached?	Yes
Global end of trial date	10 April 2020
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The primary objective was to evaluate if palonosetron (compared to placebo) could reduce the incidence of postdischarge nausea and vomiting (PDNV) in patients with high risk for PDNV in ambulatory surgery. In the high-risk group incidences of 40-50% are reported and a reduction in PDNV of 50% during the first 48 hours is clinically relevant.

Protection of trial subjects:

The study was conducted in compliance with the declarations of Helsinki and ICH guidelines, as well as regulations and laws in Sweden. The study was approved by the Ethical review board in Sweden and patients gave informed and written consent to participate.

Background therapy:

Standard postoperative care including multimodal analgesia.

Evidence for comparator: -

Actual start date of recruitment	02 May 2016
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	Sweden: 524
Worldwide total number of subjects	524
EEA total number of subjects	524

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)	412
From 65 to 84 years	112

85 years and over	0
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## Subject disposition

### Recruitment

Recruitment details:

Patients were recruited at two study sites in Sweden, Sundsvall Hospital, Sundvall and Sunderby Hospital, Luleå.

Inclusion period was 2017/03/13 to 2020/04/10

### Pre-assignment

Screening details:

Patients were first screened for inclusion BEFORE the surgical procedure/anesthesia. Patients needed to be included before surgery/anaesthesia as information and consent not can be provided in an immediate postoperative setting. Final inclusion in the interventional randomized part of the study depended on the PDNV-score post.

### Pre-assignment period milestones

Number of subjects started	524
Number of subjects completed	170

### Pre-assignment subject non-completion reasons

Reason: Number of subjects	No resources to randomize (if PDNV3-5): 8
Reason: Number of subjects	Wrong PDNV-classification: 2
Reason: Number of subjects	Low risk for PDNV: 344

### Period 1

Period 1 title	Randomisation of patients with high risk (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

### Arms

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

Arm description:

Singel dose of Palonosetron 75µg intravenous before discharge to home

Arm type	Experimental
Investigational medicinal product name	Palonosetron
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection/infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

Palonosetron 75µg intravenous

<b>Arm title</b>	Placebo
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Arm description:

Placebo Sodium Chloride 9mg/mL, 1,5 mL

Arm type	Placebo
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Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection/infusion
Routes of administration	Injection

Dosage and administration details:

1.5 ML SodiumChloride 9mg/mL

<b>Number of subjects in period 1<sup>[1]</sup></b>	Palonosetron	Placebo
Started	84	86
Completed	66	70
Not completed	18	16
Lost to follow-up	18	16

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: The inclusion in the RCT-part was a two-step procedure. Preoperatively, a broad range of patients were included and gave consent to be included in the RCT, if the PNDV score was >3 at the evaluation before discharge. Of 559 patients included, 170 was randomized.

## Baseline characteristics

### Reporting groups

Reporting group title	Palonosetron
Reporting group description:	
Singel dose of Palonosetron 75µg intravenous before discharge to home	
Reporting group title	Placebo
Reporting group description:	
Placebo Sodium Chloride 9mg/mL, 1,5 mL	

Reporting group values	Palonosetron	Placebo	Total
Number of subjects	84	86	170
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Units: years			
median	42.0	39.8	
full range (min-max)	18.3 to 79.1	18.5 to 82.1	-
Gender categorical			
Units: Subjects			
Female	74	76	150
Male	10	10	20
Smokers			
Smokers			
Units: Subjects			
Yes	11	6	17
No	73	80	153
ASA			
ASA physical status classification			
Units: Subjects			
Class 1	48	44	92
Class 2 or 3	36	42	78
History of motion sickness			
Units: Subjects			
Yes	43	46	89
No	41	40	81
Type of procedure			
Units: Subjects			

General Surgery	44	39	83
Orthopaedics	16	17	33
Urology	2	2	4
Gynaecology	15	18	33
ENT	6	10	16
Ophtalmic	1	0	1
History of PONV			
Units: Subjects			
Yes	40	48	88
No	44	38	82
Maintenance of anaesthesia			
Units: Subjects			
Volatile	52	55	107
Intravenous	32	30	62
Missing	0	1	1
Number of antiemetic prophylaxis			
Units: Subjects			
One	13	13	26
Two	53	48	101
Three	18	25	43
Nausea in PACU			
Units: Subjects			
yes	33	39	72
no	51	47	98
Rescue opioids at PACU			
Units: Subjects			
Yes	65	57	122
No	19	29	48
PDNV-score before discharge			
Units: Subjects			
PDNV 3	55	65	120
PDNV 4	25	17	42
PDNV 5	4	4	8
Trial site			
Units: Subjects			
Sundsvall	77	80	157
Sunderbyn	7	6	13
BMI			
Body Mass Index			
Units: kg m-1			
median	25.9	26.6	
full range (min-max)	19.5 to 42.8	15.6 to 41.2	-
Duration procedure			
Surgical duration "knife to last suture"			
Units: minutes			
median	58	48	
full range (min-max)	7 to 161	4 to 201	-

## Subject analysis sets

Subject analysis set title	Analysed Palonosetron
Subject analysis set type	Full analysis
Subject analysis set description:	
Subjects included in analysis randomized to Palonosetron	
Subject analysis set title	Analysed Placebo
Subject analysis set type	Full analysis
Subject analysis set description:	
Analysed patients in the placebo group	

Reporting group values	Analysed Palonosetron	Analysed Placebo	
Number of subjects	66	70	
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
Units: years			
median	42.1	45.3	
full range (min-max)	18.5 to 82.1	18.3 to 79.1	
Gender categorical			
Units: Subjects			
Female	59	64	
Male	7	6	
Smokers			
Smokers			
Units: Subjects			
Yes	7	5	
No	59	65	
ASA			
ASA physical status classification			
Units: Subjects			
Class 1	39	35	
Class 2 or 3	27	35	
History of motion sickness			
Units: Subjects			
Yes	35	38	
No	31	32	
Type of procedure			
Units: Subjects			
General Surgery	36	30	
Orthopaedics	13	15	

Urology	1	2	
Gynaecology	11	15	
ENT	4	8	
Ophtalmic	1	0	
History of PONV			
Units: Subjects			
Yes	35	38	
No	31	32	
Maintenance of anaesthesia			
Units: Subjects			
Volatile	26	26	
Intravenous	40	43	
Missing	0	1	
Number of antiemetic prophylaxis			
Units: Subjects			
One	9	9	
Two	43	41	
Three	14	20	
Nausea in PACU			
Units: Subjects			
yes	24	29	
no	44	41	
Rescue opioids at PACU			
Units: Subjects			
Yes	50	49	
No	16	21	
PDNV-score before discharge			
Units: Subjects			
PDNV 3	46	54	
PDNV 4	18	13	
PDNV 5	2	3	
Trial site			
Units: Subjects			
Sundsvall	60	65	
Sunderbyn	6	5	
BMI			
Body Mass Index			
Units: kg m-1			
median	25.6	26.5	
full range (min-max)	19.5 to 42.8	15.6 to 41.2	
Duration procedure			
Surgical duration "knife to last suture"			
Units: minutes			
median	50	49	
full range (min-max)	7 to 161	4 to 201	

## End points

### End points reporting groups

Reporting group title	Palonosetron
Reporting group description: Singel dose of Palonosetron 75µg intravenous before discharge to home	
Reporting group title	Placebo
Reporting group description: Placebo Sodium Chloride 9mg/mL, 1,5 mL	
Subject analysis set title	Analysed Palonosetron
Subject analysis set type	Full analysis
Subject analysis set description: Subjects included in analysis randomized to Palonosetron	
Subject analysis set title	Analysed Placebo
Subject analysis set type	Full analysis
Subject analysis set description: Analysed patients in the placebo group	

### Primary: Complete response

End point title	Complete response
End point description: Number of patients with no events of nausea, no events of vomit and not taking any rescue antiemetics	
End point type	Primary
End point timeframe: Discharge from ambulatory surgery until the second postoperative day (POD2)	

End point values	Analysed Palonosetron	Analysed Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	66	70		
Units: Number of patients				
Yes	32	25		

### Statistical analyses

Statistical analysis title	Complete response
Statistical analysis description: Primary analysis	
Comparison groups	Analysed Palonosetron v Analysed Placebo

Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.131
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	1.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	3.37

### Secondary: PDNV POD0

End point title	PDNV POD0
End point description:	
Patients reporting nausea or vomit	
End point type	Secondary
End point timeframe:	
On the day of procedure, after discharge	

End point values	Analysed Palonosetron	Analysed Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	66	70		
Units: Number of patients				
Yes	31	39		

### Statistical analyses

<b>Statistical analysis title</b>	PNDV POD0
Comparison groups	Analysed Palonosetron v Analysed Placebo
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.181
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	1.38

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**Secondary: PDNV POD1**

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End point title	PDNV POD1
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End point description:

Patients reporting nausea or vomit

End point type	Secondary
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End point timeframe:

On postoperative day 1 (POD1)

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End point values	Analysed Palonosetron	Analysed Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	66	70		
Units: Number of patients				
Yes	12	24		

**Statistical analyses**

<b>Statistical analysis title</b>	PDNV POD1
Comparison groups	Analysed Palonosetron v Analysed Placebo
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.033
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	0.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.19
upper limit	0.94

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**Secondary: PDNV POD2**

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End point title	PDNV POD2
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End point description:

Patients reporting nausea or vomit

End point type	Secondary
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End point timeframe:

On postoperative day 2 (POD2)

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End point values	Analysed Palonosetron	Analysed Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	66	70		
Units: Number of patients				
Yes	6	19		

## Statistical analyses

Statistical analysis title	PDNV POD2
Comparison groups	Analysed Palonosetron v Analysed Placebo
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.007
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	0.94

## Secondary: PDNV POD3

End point title	PDNV POD3
End point description:	
Patients reporting nausea or vomit	
End point type	Secondary
End point timeframe:	
On postoperative day 3 (POD3)	

End point values	Analysed Palonosetron	Analysed Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	66	70		
Units: Numer of patients				
Yes	10	9		

### Statistical analyses

<b>Statistical analysis title</b>	PDNV POD3
Comparison groups	Analysed Palonosetron v Analysed Placebo
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 1.21
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	1.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	3.2

### Secondary: PDNV POD1-POD2

End point title	PDNV POD1-POD2
End point description:	
Patients reporting nausea or vomit	
End point type	Secondary
End point timeframe:	
On the first and second postoperative days	

<b>End point values</b>	Analysed Palonosetron	Analysed Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	66	70		
Units: Number of patients				
Yes	12	27		

### Statistical analyses

<b>Statistical analysis title</b>	PDNV POD1-2
Comparison groups	Analysed Palonosetron v Analysed Placebo

Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.009
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	0.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.16
upper limit	0.78

## Secondary: Rescue Antiemetics POD0

End point title	Rescue Antiemetics POD0
End point description:	
Patients taken rescue antiemetics	
End point type	Secondary
End point timeframe:	
Day of surgery, after discharge	

End point values	Analysed Palonosetron	Analysed Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	66	70		
Units: Number of patients				
Yes	17	21		

## Statistical analyses

<b>Statistical analysis title</b>	Rescue POD0
Comparison groups	Analysed Palonosetron v Analysed Placebo
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.582
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	1.72

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**Secondary: Rescue Antiemetics POD1**

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End point title	Rescue Antiemetics POD1
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End point description:

Patients taken rescue antiemetics

End point type	Secondary
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End point timeframe:

Postoperative day 1 (POD1)

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End point values	Analysed Palonosetron	Analysed Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	66	70		
Units: Number of patients				
yes	7	15		

**Statistical analyses**

<b>Statistical analysis title</b>	Rescue POD1
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Comparison groups	Analysed Palonosetron v Analysed Placebo
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Number of subjects included in analysis	136
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Analysis specification	Pre-specified
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Analysis type	equivalence
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P-value	= 0.087
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Method	Chi-squared
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Parameter estimate	Odds ratio (OR)
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Point estimate	0.44
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Confidence interval

level	95 %
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sides	2-sided
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lower limit	0.16
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upper limit	1.15
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**Secondary: Rescue Antiemetics POD2**

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End point title	Rescue Antiemetics POD2
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End point description:

End point type	Secondary
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End point timeframe:

On the second postoperative day (POD2)

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<b>End point values</b>	Analysed Palonosetron	Analysed Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	66	70		
Units: Number of patients				
yes	2	10		

### Statistical analyses

<b>Statistical analysis title</b>	Rescue POD2
Comparison groups	Analysed Palonosetron v Analysed Placebo
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.021
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.04
upper limit	0.89

### Secondary: Rescue antiemetics POD3

End point title	Rescue antiemetics POD3
End point description:	
End point type	Secondary
End point timeframe:	
On the third postoperative day (POD3)	

<b>End point values</b>	Analysed Palonosetron	Analysed Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	66	70		
Units: Member of patients				
yes	2	5		

### Statistical analyses

<b>Statistical analysis title</b>	REscue POD3
Comparison groups	Analysed Palonosetron v Analysed Placebo
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.278
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	0.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.08
upper limit	2.17

### Secondary: Rescue antiemetics POD1-POD2

End point title	Rescue antiemetics POD1-POD2
End point description:	
End point type	Secondary
End point timeframe:	
On postoperative day 1 and 2 (POD1-POD2)	

<b>End point values</b>	Analysed Palonosetron	Analysed Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	66	70		
Units: Number of patients				
yes	8	17		

### Statistical analyses

<b>Statistical analysis title</b>	Rescue POD1-2
Comparison groups	Analysed Placebo v Analysed Palonosetron

Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.067
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	0.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.17
upper limit	1.08

### Other pre-specified: Headache

End point title	Headache
End point description:	
Patients reporting headache	
End point type	Other pre-specified
End point timeframe:	
From discharge to postoperative day 3	

End point values	Analysed Palonosetron	Analysed Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	66	70		
Units: Number of patients				
yes	25	24		

### Statistical analyses

<b>Statistical analysis title</b>	Headache
Comparison groups	Analysed Palonosetron v Analysed Placebo
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.66
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	5.36

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**Other pre-specified: Visual disturbances POD0-POD3**

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End point title	Visual disturbances POD0-POD3
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End point description:

Patients reporting visual disturbances

End point type	Other pre-specified
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End point timeframe:

Discharge to postoperative day 3

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End point values	Analysed Palonosetron	Analysed Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	66	70		
Units: Number of patients				
yes	14	8		

**Statistical analyses**

<b>Statistical analysis title</b>	Visual dist
Comparison groups	Analysed Palonosetron v Analysed Placebo
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.12
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	2.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	5.36

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**Other pre-specified: Sleeping difficulties POD0-POD1**

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End point title	Sleeping difficulties POD0-POD1
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End point description:

Patients reporting sleeping difficulties

End point type	Other pre-specified
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End point timeframe:

From discharge until postoperative day 3

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<b>End point values</b>	Analysed Palonosetron	Analysed Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	66	70		
Units: Number of patients				
yes	32	31		

### Statistical analyses

<b>Statistical analysis title</b>	Sleepingdiff
Comparison groups	Analysed Palonosetron v Analysed Placebo
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.62
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	2.33

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Until postoperative day 30

Assessment type	Systematic
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### Dictionary used

Dictionary name	SNOMED CT
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Dictionary version	SWE 221130
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### Reporting groups

Reporting group title	Palonosetron
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Reporting group description:

The groups that received the intervention in the trial

Reporting group title	Placebo
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Reporting group description: -

Serious adverse events	Palonosetron	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 84 (0.00%)	0 / 86 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Palonosetron	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 84 (3.57%)	3 / 86 (3.49%)	
Surgical and medical procedures			
Postoperative bleeding			
subjects affected / exposed	1 / 84 (1.19%)	0 / 86 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Bradycardia	Additional description: transient bradycardia (lowest heart rate 38 beats/min) immediately after administration of the study drug in a subject with a baseline heart rate of 50 beats min/m		
subjects affected / exposed	0 / 84 (0.00%)	1 / 86 (1.16%)	
occurrences (all)	0	1	
Immune system disorders			

Allergic reaction subjects affected / exposed occurrences (all)	Additional description: Allergic reaction that required a visit to the emergency department on POD1		
	0 / 84 (0.00%) 0	1 / 86 (1.16%) 1	
Gastrointestinal disorders hiccoughs subjects affected / exposed occurrences (all)	Additional description: on POD6		
	1 / 84 (1.19%) 1	0 / 86 (0.00%) 0	
Renal and urinary disorders Postoperative retention of urine subjects affected / exposed occurrences (all)	1 / 84 (1.19%) 1	1 / 86 (1.16%) 1	
Musculoskeletal and connective tissue disorders Backache subjects affected / exposed occurrences (all)	Additional description: Back pain on POD5		
	1 / 84 (1.19%) 1	0 / 86 (0.00%) 0	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported

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### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/37246062>