Clinical trial results:
Randomized clinical trial to evaluate the dose and administration time of indocyanine green in near-infrared fluorescent cholangiography during laparoscopic cholecystectomy.

Summary

EudraCT number	2022-000904-36
Trial protocol	ES
Global end of trial date	14 September 2023

Results information

Result version number	v1 (current)
This version publication date	09 June 2024
First version publication date	09 June 2024

Trial information

Trial identification

Sponsor protocol code	IBS-DOTIG-ECM-2202

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05419947
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Institute for Biomedical Research of Salamanca (IBSAL)
Sponsor organisation address	P.º de San Vicente, 182, Salamanca, Spain, 37007
Public contact	Área de Ensayos Clínicos, UICEC IBSAL, 0034 923291200 ext 55114, uicec.gestion@ibsal.es
Scientific contact	Área de Ensayos Clínicos, UICEC IBSAL, 696022264 923291200 ext 55114, uicec.gestion@ibsal.es

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 April 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 September 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study is to analyze whether there are differences between different types of doses and administration intervals of indocyanine green to obtain quality fluorescent cholangiography during laparoscopic cholecystectomy. In addition, the factors that influence the results of the technique will be sought.

Protection of trial subjects:

The project had the prior favorable report from the Ethics Committee for Drug Research of the Health Area of Salamanca. The project development was carried out in accordance with current ethical standards, the Declaration of Helsinki, and data protection legislation (Law 3/2018 and European Regulation 2016/679). Confidentiality and security of information were ensured by deleting non-anonymized data and restricting access in case of patent.

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

Actual start date of recruitment	01 July 2022
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	Spain: 200
Worldwide total number of subjects	200
EEA total number of subjects	200

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)	103
From 65 to 84 years	88
85 years and over	9

Subject disposition

Recruitment

Recruitment details:

The annual rate of LC in the two hospitals in the study is over 300 surgeries per year. In order to recruit 200 in both centres, a review waiting list will be conducted. Patients who meet the inclusion criteria will be given the necessary information and, after signing the informed consent form, will be included in the trial.

Pre-assignment

Screening details:

Patients scheduled for laparoscopic cholecystectomy who meet all inclusion criteria and none of the exclusion criteria

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1

Arm description:

Dosage and administration details: 2,5 mg >3 hours prior to surgery

Arm type	Experimental
Investigational medicinal product name	Indocyanine green
Investigational medicinal product code	3599-32-4
Other name	IC-Green
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

2,5 mg
>3 hours prior to surgery

Arm title	Group 2

Arm description:

Dosage and administration details: 2,5 mg 15-30 minutes prior to surgery

Arm type	Experimental
Investigational medicinal product name	Indocyanine green
Investigational medicinal product code	3599-32-4
Other name	IC-Green
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

2,5 mg
15-30 minutes prior to surgery

Arm title	Group 3

Arm description:

Dosage and administration details: 0,05 mg/kg >3 hours prior to surgery

Arm type	Experimental

Investigational medicinal product name	Indocyanine green
Investigational medicinal product code	3599-32-4
Other name	IC-Green
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

0,05 mg/kg
>3 hours prior to surgery

Arm title	Group 4

Arm description:

Dosage and administration details: 0,05 mg/kg 15-30 minutes prior to surgery

Arm type	Experimental
Investigational medicinal product name	Indocyanine green
Investigational medicinal product code	3599-32-4
Other name	IC-Green
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

0,05 mg/kg
15-30 minutes prior to surgery

Number of subjects in period 1	Group 1	Group 2	Group 3
Started	49	45	44
Completed	47	45	44
Not completed	2	0	0
Physician decision	1	-	-
Consent withdrawn by subject	1	-	-

Number of subjects in period 1	Group 4
Started	62
Completed	60
Not completed	2
Physician decision	1
Consent withdrawn by subject	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall

Reporting group description: -

Reporting group values	Overall	Total	
Number of subjects	200	200	
Age categorical			
Patients scheduled for laparoscopic cholecystectomy who meet all inclusion criteria and none of the exclusion criteria.			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	103	103	
From 65-84 years	88	88	
85 years and over	9	9	
Gender categorical			
Patients scheduled for laparoscopic cholecystectomy who meet all inclusion criteria and none of the exclusion criteria.			
Units: Subjects			
Female	121	121	
Male	79	79	

End points

End points reporting groups

Reporting group title	Group 1
Reporting group description:	
Dosage and administration details: 2,5 mg >3 hours prior to surgery	
Reporting group title	Group 2
Reporting group description:	
Dosage and administration details: 2,5 mg 15-30 minutes prior to surgery	
Reporting group title	Group 3
Reporting group description:	
Dosage and administration details: 0,05 mg/kg >3 hours prior to surgery	
Reporting group title	Group 4
Reporting group description:	
Dosage and administration details: 0,05 mg/kg 15-30 minutes prior to surgery	

Primary: Identification of biliary structures prior to dissection of the hepatocystic triangle

End point title	Identification of biliary structures prior to dissection of the hepatocystic triangle[1]

End point description:

Identification of biliary structures prior to dissection of the hepatocystic triangle. Number of Subject with structures

Cat 1. Identification of the cystic duct prior to dissection
Cat 2. Identification of the common bile duct prior to dissection
Cat 3. Identification of the junction of the cystic duct with the common bile duct prior to dissection
Cat 4. Identification of the union of the cystic duct with the gallbladder prior to dissection
Cat 5. Identification of the common hepatic duct prior to dissection
Cat 6. Identification of biliary anatomical variables prior to dissection

End point type	Primary

End point timeframe:

At the time of the surgical procedure

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: The results are purely descriptive and do not warrant additional statistical analysis beyond that.

End point values	Group 1	Group 2	Group 3	Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	45	44	60
Units: Subject				
number (not applicable)				
Cat 1	26	20	26	29
Cat 2	32	25	28	36
Cat 3	15	12	18	19
Cat 4	23	19	25	19
Cat 5	16	16	16	25
Cat 6	2	1	1	0

Statistical analyses

No statistical analyses for this end point

Primary: Identification of biliary structures after dissection of the hepatocystic triangle

End point title	Identification of biliary structures after dissection of the hepatocystic triangle[2]

End point description:

Identification of biliary structures after dissection of the hepatocystic triangle.

Cat 1.Identification of the cystic duct after to dissection
Cat 2. Identification of the common bile duct after to dissection
Cat 3. Identification of the junction of the cystic duct with the common bile duct after to dissection
Cat 4. Identification of the union of the cystic duct with the gallbladder after to dissection
Cat 5. Identification of the common hepatic duct after to dissection
Cat 6. Identification of biliary anatomical variables after to dissection

End point type	Primary

End point timeframe:

At the time of the surgical procedure

Notes:

[2] - 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: The results are purely descriptive and do not warrant additional statistical analysis beyond that.

End point values	Group 1	Group 2	Group 3	Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	45	44	60
Units: Subject				
number (not applicable)				
Cat 1	40	38	36	45
Cat 2	42	33	35	48
Cat 3	37	30	29	40
Cat 4	41	35	36	40
Cat 5	24	26	25	36
Cat 6	6	5	5	3

Statistical analyses

No statistical analyses for this end point

Primary: Degree of identification of biliary structures prior to dissection of the hepatocystic triangle

End point title	Degree of identification of biliary structures prior to dissection of the hepatocystic triangle[3]

End point description:

Degree of identification of biliary structures prior to dissection of the hepatocystic triangle.

The following scale will be used: 1=little, 2=sufficient, 3=quite a bit, 4=good, 5=excellent

End point type	Primary

End point timeframe:

At the time of the surgical procedure

Notes:

[3] - 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: The results are purely descriptive and do not warrant additional statistical analysis beyond that.

End point values	Group 1	Group 2	Group 3	Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	45	44	60
Units: Subject				
number (not applicable)				
1=little	13	20	12	26
2=sufficient	11	7	4	11
3=quite a bit	6	5	9	3
4=good	12	7	10	14
5=excellent	7	6	9	8

Statistical analyses

No statistical analyses for this end point

Primary: Degree of identification of biliary structures after dissection of the hepatocystic triangle

End point title	Degree of identification of biliary structures after dissection of the hepatocystic triangle[4]

End point description:

Degree of identification of biliary structures after dissection of the hepatocystic triangle.

The following scale will be used: 1=little, 2=sufficient, 3=quite a bit, 4=good, 5=excellent

End point type	Primary

End point timeframe:

At the time of the surgical procedure

Notes:

[4] - 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: The results are purely descriptive and do not warrant additional statistical analysis beyond that.

End point values	Group 1	Group 2	Group 3	Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	45	44	60
Units: Subject				
number (not applicable)				
1=little	6	6	5	13
2=sufficient	6	12	6	10

3=quite a bit	8	4	5	5
4=good	13	6	15	16
5=excellent	16	17	13	18

Statistical analyses

No statistical analyses for this end point

Primary: Extent to which fluorescence cholangiography was perceived as useful for surgery

End point title	Extent to which fluorescence cholangiography was perceived as useful for surgery[5]

End point description:

Extent to which fluorescence cholangiography was perceived as useful for surgery The following scale will be used: 0=not useful, 1=moderately useful, 2=very useful

End point type	Primary

End point timeframe:

At the time of the surgical procedure

Notes:

[5] - 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: The results are purely descriptive and do not warrant additional statistical analysis beyond that.

End point values	Group 1	Group 2	Group 3	Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	45	44	60
Units: Useful scale				
0=not useful	4	9	3	13
1=moderately useful	23	24	19	24
2=very useful	22	12	22	25

Statistical analyses

No statistical analyses for this end point

Primary: Extent to which liver fundus fluorescence (contrast between liver and ducts) was perceived as disturbing

End point title	Extent to which liver fundus fluorescence (contrast between liver and ducts) was perceived as disturbing[6]

End point description:

Extent to which liver fundus fluorescence (contrast between liver and ducts) was perceived as disturbing.

The following scale will be used: 0=no disturbance, 1=slightly disturbed, 2=disturbed visualization, but cystic-bile duct junction was clearly visible before dissection, 3=disturbed visualization and cystic-bile duct junction was only visible after dissection. dissection and 4= very disturbed: it was impossible to correctly visualize the biliary structures

End point type	Primary

End point timeframe:

At the time of the surgical procedure

Notes:

[6] - 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: The results are purely descriptive and do not warrant additional statistical analysis beyond that.

End point values	Group 1	Group 2	Group 3	Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	45	44	60
Units: Disturbing scale				
Cat 0	27	12	26	7
Cat 1	17	17	13	21
Cat 2	4	4	5	16
Cat 3	1	9	0	9
Cat 4	0	3	0	9

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The adverse event collection period in this study extends from the time of surgery until one month post-surgery

Adverse event reporting additional description:

In the DOTIG study, a total of 200 patients were enrolled. Throughout the study, 109 AEs were collected, of which 14 (12.8%) were reported as serious adverse events (SAEs). None of these SAEs showed a causal relationship with the study medication.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Valid patients

Reporting group description:

Patients scheduled for laparoscopic cholecystectomy who meet all inclusion criteria and none of the exclusion criteria.

Serious adverse events	Valid patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 196 (4.59%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma	Additional description: It refers to a type of cancer that originates in the glandular cells lining the internal and external surfaces of the body		
subjects affected / exposed	1 / 196 (0.51%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Atrial fibrillation	Additional description: Medical condition characterized by disorganized electrical impulses in the atria (the upper chambers of the heart), leading to an irregular and often rapid heartbeat. Atrial fibrillation can increase the risk of blood clots, strokes, and other heart-		
subjects affected / exposed	1 / 196 (0.51%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Heart Failure	Additional description: A chronic condition characterized by the heart's inability to pump enough blood to meet the body's needs.		

subjects affected / exposed	1 / 196 (0.51%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Hypersensitivity	Additional description: Exaggerated immune response to a specific substance, known as an allergen		
subjects affected / exposed	1 / 196 (0.51%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Acute Pancreatitis	Additional description: It refers to the sudden inflammation of the pancreas, which can range from mild and self-limiting to severe and potentially life-threatening.		
subjects affected / exposed	1 / 196 (0.51%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Abdominal pain	Additional description: Abdominal pain refers to discomfort or pain felt in the area between the chest and the pelvis.		
subjects affected / exposed	1 / 196 (0.51%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ileus paralytic	Additional description: Condition characterized by the temporary paralysis of the muscles of the intestine, which prevents the movement of food, fluid, and gas through the digestive tract		
subjects affected / exposed	1 / 196 (0.51%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholecystitis	Additional description: An inflammatory condition of the gallbladder, typically caused by the presence of gallstones blocking the cystic duct		
subjects affected / exposed	1 / 196 (0.51%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholangitis	Additional description: An inflammation of the bile ducts, which are the tubes that carry bile from the liver to the gallbladder and intestines		
subjects affected / exposed	1 / 196 (0.51%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			

Respiratory failure	Additional description: A condition in which the respiratory system fails to adequately oxygenate the blood and/or remove carbon dioxide from the body.		
subjects affected / exposed	1 / 196 (0.51%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abscess	Additional description: Localized collection of pus that can occur anywhere in the body		
subjects affected / exposed	1 / 196 (0.51%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intraabdominal fluid collection	Additional description: the accumulation of fluid within the abdominal cavity. This can occur due to various reasons such as trauma, infection, inflammation, or surgery.		
subjects affected / exposed	2 / 196 (1.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Valid patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	66 / 196 (33.67%)		
Vascular disorders			
Ecchymosis	Additional description: Ecchymosis in the surgical wound.		
subjects affected / exposed	2 / 196 (1.02%)		
occurrences (all)	2		
Phlebitis			
subjects affected / exposed	3 / 196 (1.53%)		
occurrences (all)	3		
Haematoma			
subjects affected / exposed	3 / 196 (1.53%)		
occurrences (all)	3		
Hypotension			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
General disorders and administration site conditions			

Pain			
subjects affected / exposed	2 / 196 (1.02%)		
occurrences (all)	2		
Fever			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	4 / 196 (2.04%)		
occurrences (all)	4		
Respiratory, thoracic and mediastinal disorders			
Respiratory failure			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Respiratory tract infection			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Rhinitis			
subjects affected / exposed	2 / 196 (1.02%)		
occurrences (all)	2		
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Cough			
subjects affected / exposed	2 / 196 (1.02%)		
occurrences (all)	2		
Psychiatric disorders			
Anxiety disorder			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Nervousness			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			

Dehiscence			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Accident	Additional description: Trauma caused by car accident		
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Thermal burn			
subjects affected / exposed	2 / 196 (1.02%)		
occurrences (all)	2		
Wound secretion			
subjects affected / exposed	2 / 196 (1.02%)		
occurrences (all)	2		
Cardiac disorders			
Sinus arrhythmia			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Sinus bradycardia			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Tachycardia			
subjects affected / exposed	2 / 196 (1.02%)		
occurrences (all)	2		
Nervous system disorders			
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 196 (2.04%)		
occurrences (all)	4		
Disorientation	Additional description: Time and spatial disorientation		
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Paraesthesia	Additional description: Leg paraesthesia		
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Somnolence			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		

Blood and lymphatic system disorders Coagulopathy subjects affected / exposed occurrences (all)	 1 / 196 (0.51%) 1		
Eye disorders Vision blurred subjects affected / exposed occurrences (all)	 1 / 196 (0.51%) 1		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Abdominal pain subjects affected / exposed occurrences (all) Constipation subjects affected / exposed occurrences (all) Melaena subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	 5 / 196 (2.55%) 5 1 / 196 (0.51%) 1 2 / 196 (1.02%) 3 1 / 196 (0.51%) 1 1 / 196 (0.51%) 1 14 / 196 (7.14%) 14		
Hepatobiliary disorders Acute cholecystitis necrotic subjects affected / exposed occurrences (all) Gallbladder rupture subjects affected / exposed occurrences (all) Cholelithiasis subjects affected / exposed occurrences (all)	 1 / 196 (0.51%) 1 1 / 196 (0.51%) 1 1 / 196 (0.51%) 1		

Skin and subcutaneous tissue disorders			
Subcutaneous emphysema			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Rash	Additional description: Exanthema in laparoscopic trocars		
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Hyperhidrosis			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Omphalitis			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Urinary retention	Additional description: Acute urinary retention		
subjects affected / exposed	2 / 196 (1.02%)		
occurrences (all)	2		
Musculoskeletal and connective tissue disorders			
Sacral pain			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	3		
Infections and infestations			
Abscess			
subjects affected / exposed	2 / 196 (1.02%)		
occurrences (all)	2		
Abscess intestinal			
subjects affected / exposed	2 / 196 (1.02%)		
occurrences (all)	2		
Conjunctivitis			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
COVID-19			

subjects affected / exposed	3 / 196 (1.53%)		
occurrences (all)	3		
Pharyngotonsillitis			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Infection	Additional description: Surgery site infection		
subjects affected / exposed	3 / 196 (1.53%)		
occurrences (all)	3		
Fungal infection			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Cachexia	Additional description: Post-surgery nausea and vomiting		
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		
Hyperglycaemia			
subjects affected / exposed	1 / 196 (0.51%)		
occurrences (all)	1		

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/36868593