Clinical trial results:
Dexamethasone Reduces Emesis After Major gastrointestinal Surgery (DREAMS trial) - A prospective, double-blind, multicentre, randomised control trial

Summary

EudraCT number	2010-022894-32
Trial protocol	GB
Global end of trial date	16 February 2015

Results information

Result version number	v1 (current)
This version publication date	11 November 2019
First version publication date	11 November 2019
Summary attachment (see zip file)	Dreams trial final report_signature page (DREAMS_End of trial report_signature page_Feb 2016.pdf) DREAMS End Of Trial Report_Feb 2016 (DREAMS End of Trial Report_19 Feb 2016.pdf)

Trial information

Trial identification

Sponsor protocol code	RG_10-209

Additional study identifiers

ISRCTN number	ISRCTN21973627
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	The University of Birmingham
Sponsor organisation address	Edgbaston, Birmingham, United Kingdom,
Public contact	Laura Magill, The University of Birmingham, 0044 1214159105, e.l.magill@bham.ac.uk
Scientific contact	Laura Magill, The University of Birmingham, 0044 1214159105, e.l.magill@bham.ac.uk

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	05 May 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 November 2014
Global end of trial reached?	Yes
Global end of trial date	16 February 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The DREAMS trial is a 2 stage study: i) a feasibility study and ii) a phase IV randomsied controlled trial. The objective of the feasibility study is to assess the feasibility of running the phase IV study. This pilot trial will develope effective strategies for patient identification, recruitment and follow-up in the main part of the trial. The objective of the full trial is to determine whether dexamethasone reduces postoperative nausea and vomiting in patients undergoing planned major bowel surgery and to determine it's role in future use in this category of patients.

Protection of trial subjects:

Dexamethasone is a safe and widely used drug for the purpose of reducing PONV. It is widely, but not universally used, for patients undergoing abdominal surgery. As the use of the drug in reducing PONV had not previously been studied specifically in patients undergoing bowel surgery, the DREAMS trial aimed to assess that.
Patients allocated to receive dexamethasone were administered a single IV dose of pre-operative dexamethsone.
The adverse affects of dexamethsone are well characterised and include gastrointestinal disturbances, hyperglycaemia, wound infection, wound dehiscence and anastomotic leak. All adverse effects were monitored and reported. Patients at increased risk of dexamethasone related adverse effects were excluded from this study.

Background therapy:

One other anti-emetic which all pateints were meant to have - LM to add

Evidence for comparator: -

Actual start date of recruitment	17 July 2011
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	United Kingdom: 1350
Worldwide total number of subjects	1350
EEA total number of subjects	1350

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)	631
From 65 to 84 years	690
85 years and over	29

Subject disposition

Recruitment

Recruitment details:

The first patient was recruited and randomised on 17-Jul-2011 and the last patient was randomised into the trial on 31-Jan-2014. 1350 patients were recruited from 48 centres in the UK. Of these patients, 674 were entered into the Dexamethasone arm (the intervention arm) and 676 patients in the no dexamethasone arm (control arm).

Pre-assignment

Screening details:

Of the 2894 patients assessed for eligibility, 1544 patients were excluded prior to randomisation, therefore 1350 patients were randomised into the study.

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, Investigator, Assessor

Blinding implementation details:

The randomised treatment allocation was given to the anaesthetist (or a member of their team). This randomisation allocation was not entered on the anaesthetic chart, operation record or patient notes. Dexamethasone was not prescribed nor its administration recorded on the anaesthetic or drug chart, instead, stickers were provided in the DREAMS site file which were added to the patient notes to explain that the patient is in a blinded trial.

Arms

Are arms mutually exclusive?	Yes
Arm title	Dexamethasone

Arm description:

Patients who underwent laparoscopic or open gastrointestinal resections for malignant or benign pathology were randomised, in a 1:1 ratio, between 8mg IV dexamethasone and control. All patients were to be given one additional anti-emetic at the time of induction, however, this must have not been dexamethasone. Thus, the intervention treatment arm was: 8 mg IV dexamethasone (plus one other anti-emetic of the anaesthetist’s choice) following induction of anaesthesia but prior to commencement of surgery.

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

Dosage and administration details:

The active compound of dexamethasone is Dexamethasone Sodium Phosphate. Dexamethasone administered within the trial is from standard NHS hospital stock.
There are two dexamethasone preparations available for parenteral use in the UK. In line with MHRA-guidance, changes to the labelling were made in 2010 so that both preparations are labelled to reflect the amount of dexamethasone base per volume; the two products remain different concentrations.
It is now recommended that parenteral dexamethasone is prescribed as dexamethasone base, for trial purposes 8mg dexamethasone base should be given. As dexamethasone comes in two forms of 4mg/ml and 3.3mg/ml, the anaesthetist/research investigator administering the drug will draw up the accurate volume to make up 8mg (2ml from the 4mg/ml vial and 2.4ml from the 3.3mg/ml vial).

Arm title	no Dexamethasone

Arm description:

Patients who underwent laparoscopic or open gastrointestinal resections for malignant or benign pathology were randomised, in a 1:1 ratio, between 8mg IV dexamethasone and control. All patients

were to be given one additional anti-emetic at the time of induction, however, this must have not been dexamethasone. Thus, the control arm was induction of anti-emetic of the anaesthetist's choice (not dexamethasone) prior to commencement of surgery.

Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Dexamethasone	no Dexamethasone
Started	674	676
Completed	674	676

Baseline characteristics

Reporting groups	
Reporting group title	Dexamethasone
Reporting group description:	
Patients who underwent laparoscopic or open gastrointestinal resections for malignant or benign pathology were randomised, in a 1:1 ratio, between 8mg IV dexamethasone and control. All patients were to be given one additional anti-emetic at the time of induction, however, this must have not been dexamethasone. Thus, the intervention treatment arm was: 8 mg IV dexamethasone (plus one other anti-emetic of the anaesthetist's choice) following induction of anaesthesia but prior to commencement of surgery.	
Reporting group title	no Dexamethasone
Reporting group description:	
Patients who underwent laparoscopic or open gastrointestinal resections for malignant or benign pathology were randomised, in a 1:1 ratio, between 8mg IV dexamethasone and control. All patients were to be given one additional anti-emetic at the time of induction, however, this must have not been dexamethasone. Thus, the control arm was induction of anti-emetic of the anaesthetist's choice (not dexamethasone) prior to commencement of surgery.	

Reporting group values	Dexamethasone	no Dexamethasone	Total
Number of subjects	674	676	1350
Age categorical Units: Subjects			
<50	91	97	188
50-59	128	120	248
60-69	214	223	437
70-79	189	172	361
>=80	52	64	116
Age continuous Units: years			
arithmetic mean	63.6	63.4	
standard deviation	± 13.4	± 13.5	-
Gender categorical Units: Subjects			
Female	283	284	567
Male	391	392	783
Smoking status Units: Subjects			
non-smoker	574	576	1150
smoker	100	100	200
ASA grade			
The ASA grade for all patients was collecetd at trial entry. ASA grade was a stratification variable.			
Units: Subjects			
P1	157	155	312
P2	402	405	807
P3	113	113	226
P4	2	3	5
abdominal access Units: Subjects			
laparoscopic	429	427	856
open	245	249	494

Enhanced recovery after surgery programme Units: Subjects			
Yes	611	615	1226
No	54	53	107
not known	9	8	17
duration of anesthesia categorical Units: Subjects			
<60 minutes	5	10	15
60-119 minutes	55	56	111
120-239 minutes	333	312	645
>=240 minutes	277	294	571
missing	4	4	8
type of surgery Units: Subjects			
stoma formation	8	9	17
stoma reversal	66	76	142
small bowel surgery	7	9	16
right colon resection	150	153	303
left/sigmoid colon resection	122	99	221
subtotal/total colectomy	27	22	49
rectal resection	276	297	573
other	17	9	26
missing	1	2	3
post operative analgesia Units: Subjects			
epidural	307	308	615
PCA	238	238	476
not known	68	70	138
other	50	49	99
none	11	11	22
duration of anesthesia continuous Units: minutes			
arithmetic mean	226	226	
standard deviation	± 99	± 108	-

End points

End points reporting groups

Reporting group title	Dexamethasone

Reporting group description:

Patients who underwent laparoscopic or open gastrointestinal resections for malignant or benign pathology were randomised, in a 1:1 ratio, between 8mg IV dexamethasone and control. All patients were to be given one additional anti-emetic at the time of induction, however, this must have not been dexamethasone. Thus, the intervention treatment arm was: 8 mg IV dexamethasone (plus one other anti-emetic of the anaesthetist's choice) following induction of anaesthesia but prior to commencement of surgery.

Reporting group title	no Dexamethasone

Reporting group description:

Patients who underwent laparoscopic or open gastrointestinal resections for malignant or benign pathology were randomised, in a 1:1 ratio, between 8mg IV dexamethasone and control. All patients were to be given one additional anti-emetic at the time of induction, however, this must have not been dexamethasone. Thus, the control arm was induction of anti-emetic of the anaesthetist's choice (not dexamethasone) prior to commencement of surgery.

Primary: vomiting within 24 hours post-surgery (24 hours)

End point title	vomiting within 24 hours post-surgery (24 hours)

End point description:

End point type	Primary

End point timeframe:

Primary outcome: proportion of patients who expereinced vomiting was measured within the first 24 hours post-surgery.

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	674	676		
Units: subjects				
Yes	172	223		
No	502	453		

Statistical analyses

Statistical analysis title	primary outcome - vomiting by 24 hours

Statistical analysis description:

chi squared test: proportion of patients experiencing vomiting within first 24 hours

Comparison groups	Dexamethasone v no Dexamethasone

Number of subjects included in analysis	1350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0026
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	0.7736
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.654
upper limit	0.915

Secondary: vomiting between 25-72 hours post-surgery (24 hours)

End point title	vomiting between 25-72 hours post-surgery (24 hours)

End point description:

End point type	Secondary

End point timeframe:

25-72 hours post-surgery

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	674	676		
Units: subjects				
yes	227	254		
no	447	422		

Statistical analyses

Statistical analysis title	vomiting between 25-72 hours
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1352
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	0.8964

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7763
upper limit	1.0349

Secondary: vomiting between 73-120 hours post-surgery (24 hours)

End point title	vomiting between 73-120 hours post-surgery (24 hours)

End point description:

End point type	Secondary

End point timeframe:

73-120 hours post-surgery

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	674	676		
Units: subjects				
yes	152	150		
no	522	526		

Statistical analyses

Statistical analysis title	vomiting between 73-120 hours
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.873
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	1.0163
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8332
upper limit	1.2398

Secondary: patient reported clinically important PONV (24 hours)

End point title	patient reported clinically important PONV (24 hours)

End point description:

End point type	Secondary

End point timeframe:

0-24 hours post-randomisation

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	631	624		
Units: subjects				
Yes	54	79		
No	577	545		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1255
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.02
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	0.94

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1255
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.02
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	-4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.5
upper limit	-0.7

Secondary: patient reported vomiting/retching (24 hours)

End point title	patient reported vomiting/retching (24 hours)
End point description:	

End point type	Secondary
End point timeframe:	
0-24 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	652	652		
Units: subjects				
Yes	158	212		
No	494	440		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1304
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	0.89

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone

Number of subjects included in analysis	1304
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	-8.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.2
upper limit	-3.4

Secondary: patient reported nausea (24 hours)

End point title	patient reported nausea (24 hours)

End point description:

End point type	Secondary

End point timeframe:

0-24 hours post-randomisation

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	650	650		
Units: subjects				
Yes	262	324		
No	388	326		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	no Dexamethasone v Dexamethasone
Number of subjects included in analysis	1300
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	0.81

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	0.91

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1300
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	-9.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.9
upper limit	-4.2

Secondary: patient reported nausea - VAS scale (24 hours)	
End point title	patient reported nausea - VAS scale (24 hours)
End point description: higher values indicate higher levels of nausea	
End point type	Secondary
End point timeframe: 0-24 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	251	304		
Units: subjects				
arithmetic mean (standard deviation)	37.8 (± 26.6)	41.7 (± 28.0)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone

Number of subjects included in analysis	555
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.09
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-3.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.5
upper limit	0.7

Secondary: return to any oral diet (24 hours)

End point title	return to any oral diet (24 hours)
End point description:	

End point type	Secondary
End point timeframe:	
0-24 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	673	672		
Units: subjects				
Yes	654	644		
No	19	28		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.18
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	1.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.99
upper limit	1.03

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.18
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.6
upper limit	3.3

Secondary: return to oral diet (fluids only) (24 hours)

End point title	return to oral diet (fluids only) (24 hours)
End point description:	

End point type	Secondary
End point timeframe:	
0-24 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	673	672		
Units: subjects				
Yes	234	284		
No	439	388		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	0.94

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	-7.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.7
upper limit	-2.3

Secondary: return to oral diet (diet and fluids) (24 hours)	
End point title	return to oral diet (diet and fluids) (24 hours)
End point description:	

End point type	Secondary
End point timeframe:	
0-24 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	673	672		
Units: subjects				
Yes	419	357		
No	254	315		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.07
upper limit	1.29

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	9.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.9
upper limit	14.4

Secondary: post-operative anti-emetics given (24 hours)	
End point title	post-operative anti-emetics given (24 hours)

End point description:

End point type	Secondary
End point timeframe: 0-24 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	674	676		
Units: subjects				
Yes	265	351		
No	409	325		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	0.85

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	-12.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.9
upper limit	-7.3

Secondary: number of types of post-operative anti-emetic given (24 hours)	
End point title	number of types of post-operative anti-emetic given (24 hours)
End point description:	

End point type	Secondary
End point timeframe:	
0-24 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	672	673		
Units: subjects				
arithmetic mean (standard deviation)	0.54 (± 0.76)	0.78 (± 0.88)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1345
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.32
upper limit	-0.14

Secondary: number of doses of post-operative anti-emetics given (24 hours)	
End point title	number of doses of post-operative anti-emetics given (24 hours)
End point description:	

End point type	Secondary
End point timeframe:	
0-24 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	670	671		
Units: subjects				
arithmetic mean (standard deviation)	0.77 (± 1.25)	1.07 (± 1.41)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1341
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.45
upper limit	-0.17

Secondary: patient reported clinically important PONV (72 hours)

End point title	patient reported clinically important PONV (72 hours)

End point description:

End point type	Secondary

End point timeframe:

25-72 hours post-randomisation

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	574	592		
Units: subjects				
Yes	96	93		
No	478	499		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.64
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.38

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.64
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	5.2

Secondary: patient reported vomiting/retching (72 hours)	
End point title	patient reported vomiting/retching (72 hours)
End point description:	

End point type	Secondary
End point timeframe:	
25-72 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	612	616		
Units: subjects				
Yes	194	209		
No	418	407		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1228
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.41
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.1

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1228
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.41
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	-2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.5
upper limit	3

Secondary: patient reported nausea (72 hours)

End point title	patient reported nausea (72 hours)
End point description:	
End point type	Secondary
End point timeframe:	
25-72 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	613	616		
Units: subjects				
Yes	324	349		
No	289	267		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1229
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.18
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.03

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1229
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.18
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	-3.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	1.8

Secondary: patient reported nausea - VAS scale (72 hours)

End point title	patient reported nausea - VAS scale (72 hours)

End point description:

higher scores indicate higher levels of nausea

End point type	Secondary

End point timeframe:

25-72 hours post-randomisation

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	298	324		
Units: subjects				
arithmetic mean (standard deviation)	43.8 (± 29.1)	44.5 (± 28.4)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	622
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.77
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.2
upper limit	3.9

Secondary: return to any oral diet (72 hours)

End point title	return to any oral diet (72 hours)

End point description:

End point type	Secondary

End point timeframe:

25-72 hours post-randomisation

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	658	672		
Units: subjects				
Yes	649	664		
No	9	8		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1330
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.77
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.99
upper limit	1.01

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1330
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.77
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	-0.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	1

Secondary: return to oral diet (fluids only) (72 hours)

End point title	return to oral diet (fluids only) (72 hours)
End point description:	

End point type	Secondary
End point timeframe:	
25-72 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	658	672		
Units: subjects				
Yes	120	128		
No	538	544		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1330
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.2

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone

Number of subjects included in analysis	1330
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5
upper limit	3.4

Secondary: return to oral diet (diet and fluids) (72 hours)

End point title	return to oral diet (diet and fluids) (72 hours)
End point description:	

End point type	Secondary
End point timeframe:	
25-72 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	658	672		
Units: subjects				
Yes	527	532		
No	131	140		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1330
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.68
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	1.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.07

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1330
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.68
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	5.3

Secondary: post-operative anti-emetics given (72 hours)	
End point title	post-operative anti-emetics given (72 hours)
End point description:	

End point type	Secondary
End point timeframe:	
25-72 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	674	676		
Units: subjects				
Yes	353	425		
No	321	251		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	0.91

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	-10.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.7
upper limit	-5.3

Secondary: number of types of post-operative anti-emetic given (72 hours)	
End point title	number of types of post-operative anti-emetic given (72 hours)
End point description:	

End point type	Secondary
End point timeframe:	
25-72 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	656	669		
Units: subjects				
arithmetic mean (standard deviation)	0.8 (± 0.86)	0.96 (± 0.89)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1325
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-0.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.25
upper limit	-0.06

Secondary: number of doses of post-operative anti-emetic given (72 hours)

End point title	number of doses of post-operative anti-emetic given (72 hours)
End point description:	
End point type	Secondary
End point timeframe:	
25-72 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	653	665		
Units: subjects				
arithmetic mean (standard deviation)	1.7 (± 2.45)	2.06 (± 2.61)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1318
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.009
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.64
upper limit	-0.09

Secondary: patient reported clinically important PONV (120 hours)

End point title	patient reported clinically important PONV (120 hours)

End point description:

End point type	Secondary

End point timeframe:

73-120 hours post-randomisation

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	467	455		
Units: subjects				
Yes	74	72		
No	393	383		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	922
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.99
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.35

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	922
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.99
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.7
upper limit	4.7

Secondary: patient reported vomiting/retching (120 hours)	
End point title	patient reported vomiting/retching (120 hours)
End point description:	

End point type	Secondary
End point timeframe:	
73-120 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	497	479		
Units: subjects				
Yes	132	129		
No	365	350		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	976
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.21

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	976
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.9
upper limit	5.2

Secondary: patient reported nausea (120 hours)	
End point title	patient reported nausea (120 hours)
End point description:	

End point type	Secondary
End point timeframe:	
73-120 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	495	474		
Units: subjects				
Yes	224	205		
No	271	269		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	969
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.53
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.21

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	969
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.53
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.3
upper limit	8.3

Secondary: patient reported nausea - VAS scale (!20 hours)

End point title	patient reported nausea - VAS scale (!20 hours)

End point description:

higher scores indicate higher levels of nausea

End point type	Secondary
End point timeframe: 73-120 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58	48		
Units: subjects				
arithmetic mean (standard deviation)	41.9 (± 26.3)	46.5 (± 32.5)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.42
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-4.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16
upper limit	6.7

Secondary: return to any oral diet (120 hours)

End point title	return to any oral diet (120 hours)
End point description:	

End point type	Secondary
End point timeframe: 73-120 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	555	560		
Units: subjects				
Yes	539	547		
No	16	13		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	no Dexamethasone v Dexamethasone
Number of subjects included in analysis	1115
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.56
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	1.01

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1115
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.56
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	1.3

Secondary: return to oral diet (fluids only) (120 hours)	
End point title	return to oral diet (fluids only) (120 hours)

End point description:

End point type	Secondary
End point timeframe: 73-120 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	555	560		
Units: subjects				
Yes	75	79		
No	480	481		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1115
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.77
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.28

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1115
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.77
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.6
upper limit	3.5

Secondary: return to oral diet (diet and fluids) (120 hours)	
End point title	return to oral diet (diet and fluids) (120 hours)
End point description:	
End point type	Secondary
End point timeframe:	
73-120 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	555	560		
Units: subjects				
Yes	463	465		
No	92	95		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1115
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.86
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.06

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone

Number of subjects included in analysis	1115
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.86
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4
upper limit	4.8

Secondary: post-operative anti-emetics given (120 hours)

End point title	post-operative anti-emetics given (120 hours)
End point description:	

End point type	Secondary
End point timeframe:	
73-120 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	674	676		
Units: subjects				
Yes	276	285		
No	398	391		

Statistical analyses

Statistical analysis title	Risk Ratio
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.65
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	0.97

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.1

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.65
Method	Chi-squared
Parameter estimate	Risk difference (RD)
Point estimate	-1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.5
upper limit	4.1

Secondary: number of types of post-operative anti-emetics given (120 hours)

End point title	number of types of post-operative anti-emetics given (120 hours)
End point description:	
End point type	Secondary
End point timeframe:	
73-120 hours post-randomisation	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	553	557		
Units: subjects				
arithmetic mean (standard deviation)	0.78 (± 0.90)	0.81 (± 0.94)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone

Number of subjects included in analysis	1110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.58
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.14
upper limit	0.08

Secondary: number of doses of post-operative anti-emetics given (120 hours)

End point title	number of doses of post-operative anti-emetics given (120 hours)

End point description:

End point type	Secondary

End point timeframe:

73-120 hours post-randomisation

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	553	555		
Units: subjects				
arithmetic mean (standard deviation)	2.23 (± 3.70)	2.30 (± 4.10)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1108
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.78
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-0.07

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.53
upper limit	0.39

Secondary: EQ-5D health status score (baseline)

End point title	EQ-5D health status score (baseline)
End point description:	

End point type	Secondary
End point timeframe:	
baseline	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	636	637		
Units: subjects				
arithmetic mean (standard deviation)	0.85 (± 0.19)	0.83 (± 0.21)		

Statistical analyses

Statistical analysis title	Risk Difference
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1273
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.03
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0.05

Secondary: EQ-5D health status score (discharge or 120 hours)

End point title	EQ-5D health status score (discharge or 120 hours)

End point description:

End point type	Secondary

End point timeframe:
discharge or 120 hours

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	568	561		
Units: subjects				
arithmetic mean (standard deviation)	0.54 (± 0.31)	0.52 (± 0.31)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1129
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.41
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.02
upper limit	0.05

Secondary: EQ-5D health status score (30 days)

End point title	EQ-5D health status score (30 days)

End point description:

End point type	Secondary

End point timeframe:
30 days

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	562	575		
Units: subjects				
arithmetic mean (standard deviation)	0.74 (± 0.26)	0.75 (± 0.24)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1137
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.69
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.03
upper limit	0.02

Secondary: EQ-5D VAS score (baseline)

End point title	EQ-5D VAS score (baseline)
End point description:	
End point type	Secondary
End point timeframe: baseline	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	642	640		
Units: subjects				
arithmetic mean (standard deviation)	75.7 (± 17.8)	74.7 (± 18.3)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1282
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.29
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	3

Secondary: EQ-5D VAS score (discharge or 120 hours)	
End point title	EQ-5D VAS score (discharge or 120 hours)
End point description:	
End point type	Secondary
End point timeframe: discharge or 120 hours	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	583	571		
Units: subjects				
arithmetic mean (standard deviation)	59.2 (± 22.7)	59.6 (± 21.5)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1154
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.74
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-0.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	2.1

Secondary: EQ-5D VAS score (30 days)

End point title	EQ-5D VAS score (30 days)
End point description:	
End point type	Secondary
End point timeframe:	
30 days	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	565	580		
Units: subjects				
arithmetic mean (standard deviation)	72.4 (± 18.7)	72.4 (± 18.1)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1145
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.98
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.2
upper limit	2.1

Secondary: FACIT-F total score (baseline)

End point title	FACIT-F total score (baseline)

End point description:

End point type	Secondary
End point timeframe: baseline	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	588	598		
Units: subjects				
arithmetic mean (standard deviation)	129.2 (± 22.0)	127.5 (± 23.9)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	4.3

Secondary: FACIT-F total score (discharge or 120 hours)
End point title	FACIT-F total score (discharge or 120 hours)
End point description:

End point type	Secondary
End point timeframe: discharge or 120 hours	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	523	525		
Units: subjects				
arithmetic mean (standard deviation)	103.0 (± 27.9)	102.0 (± 27.5)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1048
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.54
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	4.4

Secondary: FACIT-F total score (30 days)

End point title	FACIT-F total score (30 days)

End point description:

End point type	Secondary

End point timeframe:

30 days

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	527	527		
Units: subjects				
arithmetic mean (standard deviation)	121.4 (± 25.2)	120.4 (± 26.4)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1054
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	4.2

Secondary: EQ-5D health status score - change from baseline to discharge/120 hours

End point title	EQ-5D health status score - change from baseline to discharge/120 hours

End point description:

End point type	Secondary

End point timeframe:

change from baseline to discharge/120 hours

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	543	535		
Units: subjects				
arithmetic mean (standard deviation)	-0.32 (± 0.33)	-0.31 (± 0.31)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1078
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.88
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.04
upper limit	0.04

Secondary: EQ-5D health status score - change from baseline to 30 days

End point title	EQ-5D health status score - change from baseline to 30 days
End point description:	

End point type	Secondary
End point timeframe:	
change from baseline to 30 days	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	534	548		
Units: subjects				
arithmetic mean (standard deviation)	-0.11 (± 0.27)	-0.09 (± 0.26)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1082
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.18
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.05
upper limit	0.01

Secondary: EQ-5D VAS score - change from baseline to discharge/120 hours

End point title	EQ-5D VAS score - change from baseline to discharge/120 hours

End point description:

End point type	Secondary

End point timeframe:
change from baseline to discharge/120 hours

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	562	549		
Units: subjects				
arithmetic mean (standard deviation)	-16.04 (± 24.55)	-15.25 (± 23.44)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.58
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	2

Secondary: EQ-5D VAS score - change from baseline to 30 days

End point title	EQ-5D VAS score - change from baseline to 30 days

End point description:

End point type	Secondary

End point timeframe:
change from baseline to 30 days

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	541	556		
Units: subjects				
arithmetic mean (standard deviation)	-3.59 (± 20.99)	-2.46 (± 21.57)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	1097
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.38
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	1.4

Secondary: FACIT-F total score - change from baseline to discharge/120 hours

End point title	FACIT-F total score - change from baseline to discharge/120 hours

End point description:

End point type	Secondary

End point timeframe:

change from baseline to discharge/120 hours

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	477	484		
Units: subjects				
arithmetic mean (standard deviation)	-26.11 (± 28.47)	-26.05 (± 28.23)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone
Number of subjects included in analysis	961
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.97
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	3.5

Secondary: FACIT-F total score - change from baseline to 30 days	
End point title	FACIT-F total score - change from baseline to 30 days
End point description:	
End point type	Secondary
End point timeframe: change from baseline to 30 days	

End point values	Dexamethasone	no Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	475	481		
Units: subjects				
arithmetic mean (standard deviation)	-8.51 (± 26.46)	-7.20 (± 25.53)		

Statistical analyses

Statistical analysis title	difference in means
Comparison groups	Dexamethasone v no Dexamethasone

Number of subjects included in analysis	956
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.43
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.6
upper limit	2

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

The SAEs were collected for all patients in the study from the first trial treatment to 30 days after the last trial treatment.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	4

Reporting groups

Reporting group title	Dexamethasone

Reporting group description:

Patients who underwent laparoscopic or open gastrointestinal resections for malignant or benign pathology were randomised, in a 1:1 ratio, between 8mg IV dexamethasone and control. All patients were to be given one additional anti-emetic at the time of induction, however, this must have not been dexamethasone. Thus, the intervention treatment arm was: 8 mg IV dexamethasone (plus one other anti-emetic of the anaesthetist's choice) following induction of anaesthesia but prior to commencement of surgery.

Reporting group title	no Dexamethasone

Reporting group description:

Patients who underwent laparoscopic or open gastrointestinal resections for malignant or benign pathology were randomised, in a 1:1 ratio, between 8mg IV dexamethasone and control. All patients were to be given one additional anti-emetic at the time of induction, however, this must have not been dexamethasone. Thus, the control arm was induction of anti-emetic of the anaesthetist's choice (not dexamethasone) prior to commencement of surgery.

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: Non-serious adverse events were not collected within this trial.

Serious adverse events	Dexamethasone	no Dexamethasone	
Total subjects affected by serious adverse events			
subjects affected / exposed	162 / 669 (24.22%)	155 / 666 (23.27%)	
number of deaths (all causes)	7	7	
number of deaths resulting from adverse events			
Vascular disorders			
Hematoma			
subjects affected / exposed	2 / 669 (0.30%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemorrhage			
subjects affected / exposed	7 / 669 (1.05%)	8 / 666 (1.20%)	
occurrences causally related to treatment / all	1 / 7	2 / 8	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hypotension			

subjects affected / exposed	2 / 669 (0.30%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic haematoma			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Ascites			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delayed wound healing			
subjects affected / exposed	2 / 669 (0.30%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central Line infection			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epidural leak			
subjects affected / exposed	1 / 669 (0.15%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multi organ failure			
subjects affected / exposed	1 / 669 (0.15%)	2 / 666 (0.30%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Peristomal fistula with leak			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			

subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drowning			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Reproductive system and breast disorders			
Perineal pain			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Apnoea			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspiration			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary embolism			
subjects affected / exposed	3 / 669 (0.45%)	3 / 666 (0.45%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	1 / 669 (0.15%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Respiratory failure			
subjects affected / exposed	2 / 669 (0.30%)	2 / 666 (0.30%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Paranoia			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Derranged Bloods			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Low sodium			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Anastomotic leak			
subjects affected / exposed	14 / 669 (2.09%)	25 / 666 (3.75%)	
occurrences causally related to treatment / all	7 / 14	13 / 25	
deaths causally related to treatment / all	0 / 1	0 / 2	
Bowel Perforation			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Catheter pain			

subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall and facial trauma			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			
subjects affected / exposed	2 / 669 (0.30%)	4 / 666 (0.60%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Other - Collection at rectal stump			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Other - Spleen laceration during surgery			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic collections			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Bladder Injury			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	13 / 669 (1.94%)	10 / 666 (1.50%)	
occurrences causally related to treatment / all	8 / 13	7 / 10	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac disorders			
Acute Coronary Syndrome			

subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	1 / 669 (0.15%)	2 / 666 (0.30%)	
occurrences causally related to treatment / all	1 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	2 / 669 (0.30%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Cardiac failure			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular systolic dysfunction			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	2 / 669 (0.30%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shortness of Breath			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Dizziness			

subjects affected / exposed	2 / 669 (0.30%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal Collection			
subjects affected / exposed	0 / 669 (0.00%)	2 / 666 (0.30%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain			
subjects affected / exposed	5 / 669 (0.75%)	14 / 666 (2.10%)	
occurrences causally related to treatment / all	0 / 5	2 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adhesions causing small bowel obstruction			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adhesions to small bowel			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Pain			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bowel Obstruction			
subjects affected / exposed	12 / 669 (1.79%)	6 / 666 (0.90%)	
occurrences causally related to treatment / all	0 / 12	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bruising of Stoma			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			

subjects affected / exposed	0 / 669 (0.00%)	4 / 666 (0.60%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	3 / 669 (0.45%)	3 / 666 (0.45%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Distended Abdomen			
subjects affected / exposed	0 / 669 (0.00%)	2 / 666 (0.30%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fistula			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
High Stoma Output			
subjects affected / exposed	6 / 669 (0.90%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	1 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	13 / 669 (1.94%)	18 / 666 (2.70%)	
occurrences causally related to treatment / all	0 / 13	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 1	
Jejunal perforation			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	5 / 669 (0.75%)	3 / 666 (0.45%)	
occurrences causally related to treatment / all	1 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal discharge			

subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulceration with haemorrhage			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Peritonitis			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Rectal stump dehiscence			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small bowel obstruction			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stoma complication			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			

subjects affected / exposed	4 / 669 (0.60%)	7 / 666 (1.05%)	
occurrences causally related to treatment / all	0 / 4	2 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acalculous Cholecystitis			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Other - Rectovaginal fistula			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical emphysema			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney infection			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	2 / 669 (0.30%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	

Urinary retention			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal Infection			
subjects affected / exposed	2 / 669 (0.30%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			
subjects affected / exposed	3 / 669 (0.45%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	1 / 3	1 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Catheter Infection			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	1 / 669 (0.15%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	8 / 669 (1.20%)	19 / 666 (2.85%)	
occurrences causally related to treatment / all	3 / 8	5 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Candida infection			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	3 / 669 (0.45%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	1 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			

subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	1 / 669 (0.15%)	2 / 666 (0.30%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stoma site infection			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	10 / 669 (1.49%)	8 / 666 (1.20%)	
occurrences causally related to treatment / all	6 / 10	4 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal infection			
subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	48 / 669 (7.17%)	47 / 666 (7.06%)	
occurrences causally related to treatment / all	37 / 48	32 / 47	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 669 (0.00%)	1 / 666 (0.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hyperparathyroidism			

subjects affected / exposed	1 / 669 (0.15%)	0 / 666 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Dexamethasone	no Dexamethasone	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 669 (0.00%)	0 / 666 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 May 2011	Protocol version 2.0 28/APR/2011. Substantial changes: Pilot study added to trial design.
26 November 2013	Protocol version 3.0 24/Oct/2013. Substantial changes: Clarification of sample size from 950 to 1320 patients; Clarification of primary outcome to 'the proportion of patients experiencing vomiting within 24 hours post-surgery'; Addition of secondary outcome 'number of episodes of vomiting post-surgery'.
30 January 2015	Protocol version 4.0 20/Jan/2015. Substantial changes: Definition of end of trial to be no later than 1 year after the last visit of the last patient undergoing the trial.

Notes:

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/28420629