Clinical trial results:
Are phrophylactic antibiotics necessary before laparoscopic living kidney donation? A double blind, randomised, controlled trial.

Summary

EudraCT number	2012-000942-36
Trial protocol	GB
Global end of trial date	12 July 2016

Results information

Result version number	v1 (current)
This version publication date	25 August 2019
First version publication date	25 August 2019
Summary attachment (see zip file)	FINAL REPORT (POWAR_NIHR_report-Final.pdf)

Trial information

Trial identification

Sponsor protocol code	POWAR

Additional study identifiers

ISRCTN number	ISRCTN71141360
ClinicalTrials.gov id (NCT number)	NCT02089568
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Guy's and St Thomas' NHS Foundation Trust
Sponsor organisation address	Great Maze Pond, London, United Kingdom, SE19RT
Public contact	Nizam Mamode, Guy's & St Thomas' NHS Foundation Trust, 0044 02071888476, nizam.mamode@gstt.nhs.uk
Scientific contact	Nizam Mamode, Guy's & St Thomas' NHS Foundation Trust, 0044 02071888476, nizam.mamode@gstt.nhs.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	12 July 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 July 2016
Global end of trial reached?	Yes
Global end of trial date	12 July 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The principal question is whether a single dose of antibiotic prior to donating a kidney reduces infections within 30 days of surgery.

Protection of trial subjects:

The IMP or Placebo will be administered intravenously at induction of anaesthesia for donor nephrectomy.

Background therapy:

n/a

Evidence for comparator: -

Actual start date of recruitment	01 October 2012
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: 295
Worldwide total number of subjects	295
EEA total number of subjects	295

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)	295
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited from 5 clinical sites in the UK between 2012 and 2016.

Pre-assignment

Screening details:

Inclusion Criteria
Male and Female patients (over 18 years) undergoing hand-assisted laparoscopic donor nephrectomy Patients who have given written informed consent to participate Patients whose first language is not English will be included; they comprise a significant part of our patient population and we will use translation services as is ou

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

Blinding implementation details:

Matching intravenous solution will be provided for placebo.

Arms

Are arms mutually exclusive?	Yes
Arm title	ACTIVE - co-amoxiclav,

Arm description:

Active IMP will be given at induction of anaesthesia prior to laparoscopic donor nephrectomy.

Arm type	Experimental
Investigational medicinal product name	Co-Amoxiclav
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

1.2g gi ven intravenously a induction of anaesthesia

Arm title	PLACEBO

Arm description:

Placebo administered as Intravenous injection on induction of anaesthesia.

Arm type	Placebo
Investigational medicinal product name	0.9% Normal Saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as single intravenous injection at induction of anaesthesia

Number of subjects in period 1	ACTIVE - co-amoxiclav,	PLACEBO
Started	149	146
Completed	144	141
Not completed	5	5
Physician decision	-	1
Received antibiotics inadvertantly	2	-
Required antibiotics	-	2
Surgery cancelled	3	2

Baseline characteristics

Reporting groups	
Reporting group title	ACTIVE - co-amoxiclav,
Reporting group description:	
Active IMP will be given at induction of anaesthesia prior to laparoscopic donor nephrectomy.	
Reporting group title	PLACEBO
Reporting group description:	
Placebo administered as Intravenous injection on induction of anaesthesia.	

Reporting group values	ACTIVE - co-amoxiclav,	PLACEBO	Total
Number of subjects	149	146	295
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	149	146	295
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	66	58	124
Male	83	88	171

End points

End points reporting groups

Reporting group title	ACTIVE - co-amoxiclav,
Reporting group description:	
Active IMP will be given at induction of anaesthesia prior to laparoscopic donor nephrectomy.	
Reporting group title	PLACEBO
Reporting group description:	
Placebo administered as Intravenous injection on induction of anaesthesia.	

Primary: Clinical Endpoint

End point title	Clinical Endpoint[1]

End point description:

The primary outcome measure will be a composite endpoint of any infection; this will include surgical site infections as well as urinary tract, respiratory and any other infections, within 30 days of surgery.
Specifically, the primary endpoint will be defined as the occurrence of any of the following:
Purulent drainage from the incision site, confirmed on microbiological testing (significant bacterial growth and pus cells present)
Positive culture of any fluid aspirated from the surgical site
At least two of the following at the incision site: fever, pain, swelling, redness, heat and either the wound is opened by the surgeon or the clinician diagnoses an infection
Dehiscence of the surgical wound
Evidence of deep infection at reoperation or radiologically
Symptomatic urinary tract infection (dysuria, fever) with culture positive MSU including pyuria
Symptomatic respiratory tract infection (fever, productive cough, dsyp

End point type	Primary

End point timeframe:

Within 30 days of surgery.

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: Please see attached report for results.

End point values	ACTIVE - co-amoxiclav,	PLACEBO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	144	141		
Units: whole	144	141		

Attachments (see zip file)	RESULTS/UH report POWAR Jan 2018.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Secondary clinical endpoint

End point title	Secondary clinical endpoint

End point description:

Secondary endpoints will include ultrasonic evidence of wound healing, length of hospital stay,

readmission rates, antibiotic associated side effects (including diarrhoea and allergic reactions), return to work and normal activities, quality of life and relative costs.

End point type	Secondary

End point timeframe:

within 30 days post surgery

End point values	ACTIVE - co-amoxiclav,	PLACEBO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	144	141		
Units: whole	144	141		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Until 30 days post surgery	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups	
Reporting group title	ACTIVE GROUP
Reporting group description: -	
Reporting group title	PLACEBO GROUP
Reporting group description: -	

Serious adverse events	ACTIVE GROUP	PLACEBO GROUP	
Total subjects affected by serious adverse events			
subjects affected / exposed	21 / 150 (14.00%)	22 / 149 (14.77%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Fluid retention			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Bowel resection			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 150 (0.00%)	2 / 149 (1.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			

subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	9 / 150 (6.00%)	4 / 149 (2.68%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound haematoma			
subjects affected / exposed	2 / 150 (1.33%)	2 / 149 (1.34%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 150 (0.00%)	2 / 149 (1.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 150 (0.67%)	2 / 149 (1.34%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (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			
Shortness of breath			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Urinary tract infection			
subjects affected / exposed	1 / 150 (0.67%)	1 / 149 (0.67%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	2 / 150 (1.33%)	1 / 149 (0.67%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	1 / 150 (0.67%)	1 / 149 (0.67%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis A			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected haematoma			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fat necrosis			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Morganella infection			

subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia and rash			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal infection			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Admission to hospital for Abdominal subcutaneous collection			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	ACTIVE GROUP	PLACEBO GROUP	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	72 / 150 (48.00%)	82 / 149 (55.03%)	
Vascular disorders			
Hypotensive			
subjects affected / exposed	3 / 150 (2.00%)	5 / 149 (3.36%)	
occurrences (all)	3	5	
Haematoma			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Vasovagal			
subjects affected / exposed	0 / 150 (0.00%)	2 / 149 (1.34%)	
occurrences (all)	0	2	
Loss of conciousness: Impression vasovagal on background of hypovolaemia and opiate excess			

subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
epigastric artery bleeding and rectus sheath haematoma requiring coiling			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Hb drop overnight			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Raised blood pressure			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Surgical and medical procedures			
Post operative ileus			
subjects affected / exposed	0 / 150 (0.00%)	3 / 149 (2.01%)	
occurrences (all)	0	3	
soft palate laceration repair			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Post operative pain			
subjects affected / exposed	2 / 150 (1.33%)	1 / 149 (0.67%)	
occurrences (all)	2	1	
post op surgical emphysema			
subjects affected / exposed	0 / 150 (0.00%)	2 / 149 (1.34%)	
occurrences (all)	0	2	
Recent self drainage of small subcutaneous pus collection			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Midline wound slightly open			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Ongoing pain and post- operative ileus			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Wound seroma- drained			

subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	2	
Surgical evacuation of haematoma			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Surgical wound feeling 'tight' after prolonged movement			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
SPLENIC INJURY INTRAOP			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Middle port site (not the lateral one) superficailly broken down			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Surgical emphysema			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Port site redressed as reported bleeding			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Contrast CT for increased pain in surgical site			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
USS of surgical site			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Aspiration of anechoic simple collection just superior to the Pfannenstiel incision, separate to bla			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Itchiness			

subjects affected / exposed	3 / 150 (2.00%)	3 / 149 (2.01%)	
occurrences (all)	3	3	
Feeling unwell			
subjects affected / exposed	2 / 150 (1.33%)	0 / 149 (0.00%)	
occurrences (all)	2	0	
Toothache			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Patient appears 'puffy' and reports feeling bloated			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Increased temperature			
subjects affected / exposed	1 / 150 (0.67%)	2 / 149 (1.34%)	
occurrences (all)	1	2	
Tiredness			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
WEAK VOICE			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Immune system disorders			
Red patches noted on patient's chest thta seemed like dilated blood vessels (shortly after having cy			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Allergic reaction across wound			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Allergy to wound dressing			
subjects affected / exposed	2 / 150 (1.33%)	0 / 149 (0.00%)	
occurrences (all)	2	0	
Anaphylaxis to contrast media			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Reproductive system and breast disorders			

Testicular pain			
subjects affected / exposed	1 / 150 (0.67%)	4 / 149 (2.68%)	
occurrences (all)	1	4	
Unusual PV bleeding			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Swelling of sotum and penis and discolourations			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Mild swelling in the left testicle with no bruising			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Itchiness around the foreskin			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Chest infection			
subjects affected / exposed	1 / 150 (0.67%)	1 / 149 (0.67%)	
occurrences (all)	1	1	
hypoxia due to basal atelectasis. CTPA -ve			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
postoperative hypoxia negative CTPA			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Pleuritic CP with left shoulder pain			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Pneumoperitoneum on right, effusion left base			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
cough - productive small volume green phlegm			

subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Reduced air entry both bases with low grade pyrexia			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Post op atelectasis			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Shortness fo breath, chest auscultation- quiet bases			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Discomfort and phlegm in centre of chest when breathing in - not when eating			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Sats dropped but improved on exercise			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Reduced air entry at bases			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Low in mood			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Investigations			
low sodium			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Ultrasound Doppler right leg (NAD)			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			

PERI UVULA ERYTHEMA				
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)		
occurrences (all)	0	1		
Wound related pain on movement				
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)		
occurrences (all)	0	1		
Small superficial collections				
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)		
occurrences (all)	0	1		
handport haematoma requiring evacuation				
subjects affected / exposed	2 / 150 (1.33%)	0 / 149 (0.00%)		
occurrences (all)	2	0		
Wound pain				
subjects affected / exposed	4 / 150 (2.67%)	2 / 149 (1.34%)		
occurrences (all)	4	2		
Shoulder pain				
subjects affected / exposed	1 / 150 (0.67%)	2 / 149 (1.34%)		
occurrences (all)	2	2		
On-going left flank discomfort +occassional sharp pains- eg on walking				
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)		
occurrences (all)	1	0		
Pain in the right para vertebral region, , around the apex of the scapula, the pain increase with mo				
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)		
occurrences (all)	1	0		
Mild surgical emphysema left abdomen				
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)		
occurrences (all)	1	0		
Intermittent pain in right calf				
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)		
occurrences (all)	1	0		
Superficial haematoma 1cm bigger than previously				

subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
'Slow healing at the left lateral working port			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Pain near left lateral port site			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	2	0	
post operative haematoma			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Superficial collection below her vertical umbilical wound- managed conservatively (8x5x3 cms on 13/1			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Pain			
subjects affected / exposed	0 / 150 (0.00%)	2 / 149 (1.34%)	
occurrences (all)	0	2	
WOUND SEROMA			
subjects affected / exposed	2 / 150 (1.33%)	0 / 149 (0.00%)	
occurrences (all)	2	0	
Midline incisiona paraincisional swelling			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Intermittent pain in remaining kidney- new onset			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
'Stingy' and 'sore' surgical site			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Ultrasound of surgical site- haemoatoma			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Small monocryl knot			

subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Right lateral aspect anterior abdominal wound swelling- small fluid collection 15x12mm on USS			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
ECGs show the T wave in lead III has inverted and is now upright			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Chest Pain			
subjects affected / exposed	2 / 150 (1.33%)	1 / 149 (0.67%)	
occurrences (all)	2	1	
Tachycardia			
subjects affected / exposed	3 / 150 (2.00%)	0 / 149 (0.00%)	
occurrences (all)	3	0	
Palpitations associated anterior T wave inversion on serial ECGs			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Migraine			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Faint episode			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	2	
Dizziness			
subjects affected / exposed	1 / 150 (0.67%)	2 / 149 (1.34%)	
occurrences (all)	1	2	
Insomnia			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Depression			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	

Panic attack			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
'Lightheadedness'			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Hallucinations			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Pins and needles over lateral aspect of left thigh- occasional episodes and improving			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Slight neutrophilia			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Cornial abrasion to right eye sustained during operation.			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
Increased floaters in vision			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Red itchy eye on right side which has been washed out this morning: mild exposure keratopathy			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Abdominal bloating			
subjects affected / exposed	8 / 150 (5.33%)	7 / 149 (4.70%)	
occurrences (all)	9	7	
Pain in Abdominal area			

subjects affected / exposed	6 / 150 (4.00%)	16 / 149 (10.74%)	
occurrences (all)	6	20	
Chlorhexidine allergy on abdomen			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	0	
complex incisional subcutaneous haematoma			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
anechoic collection on abdominal ultrasound			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	0	0	
Consitpation			
subjects affected / exposed	8 / 150 (5.33%)	7 / 149 (4.70%)	
occurrences (all)	11	8	
Nausea and/or vomiting			
subjects affected / exposed	13 / 150 (8.67%)	18 / 149 (12.08%)	
occurrences (all)	13	19	
Diarrhoea			
subjects affected / exposed	2 / 150 (1.33%)	2 / 149 (1.34%)	
occurrences (all)	2	2	
Loss of appetite			
subjects affected / exposed	0 / 150 (0.00%)	2 / 149 (1.34%)	
occurrences (all)	0	2	
Intermittent "burning sensation" abdomen			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Capsular splenic tear			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Upset stomach			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
CT abdo pelvis today- small collection left side with no other significant findings			

subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Ileus			
subjects affected / exposed	1 / 150 (0.67%)	2 / 149 (1.34%)	
occurrences (all)	1	2	
PCA induced nausea and vomiting			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
slightly elevated blood sugar			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
small bowel obstruction			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Fluid collection			
subjects affected / exposed	9 / 150 (6.00%)	1 / 149 (0.67%)	
occurrences (all)	9	1	
splenic tear.			
subjects affected / exposed	0 / 150 (0.00%)	2 / 149 (1.34%)	
occurrences (all)	0	2	
Irregular bowels			
subjects affected / exposed	1 / 150 (0.67%)	1 / 149 (0.67%)	
occurrences (all)	1	1	
Loose Stools			
subjects affected / exposed	2 / 150 (1.33%)	0 / 149 (0.00%)	
occurrences (all)	2	0	
Gastroenteritis			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Does not have full bowel sensation			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			
Mild LFT raise			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	

Skin and subcutaneous tissue disorders			
Hand oedema			
subjects affected / exposed	1 / 150 (0.67%)	1 / 149 (0.67%)	
occurrences (all)	1	1	
Swelling of upper lip			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Skin RIF tender to palpation. Some stretching on left flank			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Bulge L flank			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
SKIN IRRITATION FROM DRESSING			
subjects affected / exposed	1 / 150 (0.67%)	1 / 149 (0.67%)	
occurrences (all)	1	1	
rash			
subjects affected / exposed	1 / 150 (0.67%)	1 / 149 (0.67%)	
occurrences (all)	1	1	
Rash over body and flexural area rashes. Itchy and blanching.			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Itchy rash to upper thigh. GP prescribed Daktacort cream ?fungal infection			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
'Lump' around surgical scar			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
swollen testicle and groin pain			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
RENAL COLIC			

subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Frothy urine			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Sensation of being unable to empty his bladder			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Elevated creatinine			
subjects affected / exposed	0 / 150 (0.00%)	3 / 149 (2.01%)	
occurrences (all)	0	3	
Raised CRP			
subjects affected / exposed	2 / 150 (1.33%)	1 / 149 (0.67%)	
occurrences (all)	2	1	
Urinary retention requiring re urinary catheterisation			
subjects affected / exposed	1 / 150 (0.67%)	1 / 149 (0.67%)	
occurrences (all)	1	1	
VISIBLE HAEMATURIA			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Urine was slow to start with post operation, now normal flow			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Urinary urgency			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Low urine output			
subjects affected / exposed	2 / 150 (1.33%)	0 / 149 (0.00%)	
occurrences (all)	2	0	
No difficultly in PU but does not have normal full sensation and has to strain slightly			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	2	0	
Creatinine 162			

subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Suspected urine infection. Given 5/7of Co-Amoxiclav antibiotics			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Urine dip- leukocytes +++ and rising CRP.			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Muscular neck pain			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Sharp pain right hip			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Some minor aches left of wound, under rib cage +ocassionally tip of left shoulder			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Xray of right shoulder- calcification of the soft tissues around the shoulder joint likely to be chr			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
intermittent left flank pain and left testicular swelling			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Discomfort in groin			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Impreson Musculoskeletal chest pain			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Backache			

subjects affected / exposed	2 / 150 (1.33%)	0 / 149 (0.00%)	
occurrences (all)	2	0	
Mildly antalgic gait			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Wound infection with/without ooze			
subjects affected / exposed	10 / 150 (6.67%)	15 / 149 (10.07%)	
occurrences (all)	11	15	
Generally unwell	Additional description: Commenced antibiotics		
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Incision and evacuation of subcutaneous abscess			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
CRP elevated			
subjects affected / exposed	2 / 150 (1.33%)	2 / 149 (1.34%)	
occurrences (all)	2	2	
Pyrexia			
subjects affected / exposed	12 / 150 (8.00%)	7 / 149 (4.70%)	
occurrences (all)	12	7	
Ulcer on palate			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Sore throat			
subjects affected / exposed	1 / 150 (0.67%)	1 / 149 (0.67%)	
occurrences (all)	1	1	
Pneumonia			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Cold (viral)			
subjects affected / exposed	1 / 150 (0.67%)	1 / 149 (0.67%)	
occurrences (all)	1	1	
Feels hot and sweaty. One episode of ?rigors			

subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Bladder irritation			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
UTI			
subjects affected / exposed	1 / 150 (0.67%)	2 / 149 (1.34%)	
occurrences (all)	1	2	
suspected viral infection			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Evidence of consolidation on CXR, coughing up sputum of unknown colour and temperature 01/02/2016-g			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Flu			
subjects affected / exposed	2 / 150 (1.33%)	0 / 149 (0.00%)	
occurrences (all)	2	0	
Hot and cold sweats at night			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	1	
Bloody ooze from midline wound			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Slight runny nose			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Shivering and sweaty			
subjects affected / exposed	1 / 150 (0.67%)	0 / 149 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Pain in right shoulder charcterised by reduced range of movement			
subjects affected / exposed	0 / 150 (0.00%)	1 / 149 (0.67%)	
occurrences (all)	0	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