Clinical trial results:
A controlled randomized, open-label, multi-centre study evaluating if a steroid-free immunosuppressive protocol, based on single dose ATG-induction, low tacrolimus-dose and therapeutic drug monitoring of mycophenolate mofetil, reduces the incidence of new onset diabetes after transplantation, in comparison with a standard steroid-based protocol with low-dose tacrolimus.

Summary

EudraCT number	2012-000451-13
Trial protocol	SE DK
Global end of trial date	01 May 2019

Results information

Result version number	v1 (current)
This version publication date	15 June 2021
First version publication date	15 June 2021
Summary attachment (see zip file)	SAILOR CSR (SAILOR CSR_dk_210520.pdf)

Trial information

Trial identification

Sponsor protocol code	1201

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Transplant Institute, Sahlgrenska University Hospital
Sponsor organisation address	Bruna stråket 5, Göteborg, Sweden, 41346
Public contact	Studycoordinator, Transplant Institute, Sahlgrenska University Hospital , 46 313421000, per.lindner@vgregion.se
Scientific contact	Studycoordinator, Transplant Institute, Sahlgrenska University Hospital , 0735514384 313421000, per.lindner@vgregion.se

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	10 June 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 May 2019
Global end of trial reached?	Yes
Global end of trial date	01 May 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The cumulative incidence of NODAT (new onset of diabetes after transplantation) 12 months after transplantation as defined by the ADA-criteria (2012).
Arm A. Steroid-free low-TAC arm:
Thymoglobuline® induction (2,5 mg/kg, pre-/peroperatively day 0, 2,5 mg/kg day 1)
+ Advagraf® (conc.: 5-10 ng/ml, after 3 months 4-7, started postop. day 1)
+ MMF 1gx2 (controlled by a single AUC measurement day 7 with a target AUC between 40 and 60 mg.h/L)
+ steroids day 0 (250 mg methylprednisolon iv. before start of Thymoglobuline infusion and day 1 50 mg methylprednisolon iv. before start of Thymoglobuline infusion)
Arm B. Standard low-TAC arm:
Simulect® induction 20mg (day 0 and day 4)
+ Advagraf® (conc.: 5-10 ng/ml, after 3 months 4-7ng/ml, started per hospital practice)
+ MMF 1gx2 (controlled by AUC measurements to 40-60 mg.h/L)
+ steroids according to hospital practice but not less than 5 mg prednisolone daily after 6 months.

Protection of trial subjects:

Interim safety analyses (looking at composite measure of freedom from acute rejection, graft survival, and patient survival) was conducted when 50 patients had been observed for 6 months. The Data Monitoring Committee performed safety analyses and had authority to recommend discontinued inclusion in the study to the sterring group. Please see synopsis for more information.

Background therapy: -

Evidence for comparator:

Comparator chosen was the standard of care. Please see synopsis for more information.

Actual start date of recruitment	01 June 2012
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy, Scientific research
Long term follow-up duration	3 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 75
Country: Number of subjects enrolled	Sweden: 148
Worldwide total number of subjects	223
EEA total number of subjects	223

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)	178
From 65 to 84 years	45
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

222 subjects were planned to be enrolled in total; 224 were actually randomized and 222 received a transplant as well as at least one study medication and attended at least one follow-up visit.

Pre-assignment

Screening details:

Please see summary report.

Period 1

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

Blinding implementation details:

Blinding is not relevant as this was an open study. However, patient identity and treatment assignment were concealed to the Primary Endpoint Committee, two independent nephrologists who assessed the accuracy of the PTDM diagnosis, and to two pathologists, who centrally evaluated all transplant biopsies.

Arms

Are arms mutually exclusive?	Yes
Arm title	Steroid avoidance

Arm description:

Induction with ATG (Thymoglobuline®; Sanofi AB) at 2.5 mg/kg peroperatively before perfusion at day 0, and day 1; methylprednisolone bolus (Solu-Medrol®; Pfizer) 250 mg before the first ATG dose and 50 mg before the second ATG dose, and maintenance treatment based on prolonged-release low-dose tacrolimus (Advagraf®; Astellas Pharma), starting dose 0.2 mg/kg once daily with target trough levels 5-10 ng/ml within first three months and thereafter 4-7 ng/ml, and MMF 1g twice a day controlled by a single area under the curve (AUC) measurement on day 10±5 with target AUC 40-60 mg*h/L.

Arm type	Experimental
Investigational medicinal product name	Thymoglobulin (Anti-thymocyte globulin)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for infusion
Routes of administration	Intraventricular use

Dosage and administration details:

ATG (Thymoglobuline®; Sanofi AB) at 2.5 mg/kg peroperatively before perfusion at day 0, and day 1

Arm title	Steroid maintenance (standard of care)

Arm description:

Induction with basiliximab (Simulect®; Novartis) at 20 mg on day 0 and day 4; methylprednisolone 250-500 mg day 0 before reperfusion, according to the local center practice, and maintenance treatment as in SA-arm plus prednisolone in doses by local center practice, but not less than the final dose of 5 mg daily.

Arm type	Active comparator
Investigational medicinal product name	Basiliximab (Simulect)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intravenous use, Intravenous bolus use

Dosage and administration details:

Induction with basiliximab (Simulect®; Novartis) at 20 mg on day 0 and day

Number of subjects in period 1[1]	Steroid avoidance	Steroid maintenance (standard of care)
Started	113	109
Completed	113	109

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Please see the attached synposis for more information.

Baseline characteristics

Reporting groups	
Reporting group title	Steroid avoidance
Reporting group description:	
Induction with ATG (Thymoglobuline®; Sanofi AB) at 2.5 mg/kg peroperatively before perfusion at day 0, and day 1; methylprednisolone bolus (Solu-Medrol®; Pfizer) 250 mg before the first ATG dose and 50 mg before the second ATG dose, and maintenance treatment based on prolonged-release low-dose tacrolimus (Advagraf®; Astellas Pharma), starting dose 0.2 mg/kg once daily with target trough levels 5-10 ng/ml within first three months and thereafter 4-7 ng/ml, and MMF 1g twice a day controlled by a single area under the curve (AUC) measurement on day 10±5 with target AUC 40-60 mg*h/L.	
Reporting group title	Steroid maintenance (standard of care)
Reporting group description:	
Induction with basiliximab (Simulect®; Novartis) at 20 mg on day 0 and day 4; methylprednisolone 250-500 mg day 0 before reperfusion, according to the local center practice, and maintenance treatment as in SA-arm plus prednisolone in doses by local center practice, but not less than the final dose of 5 mg daily.	

Reporting group values	Steroid avoidance	Steroid maintenance (standard of care)	Total
Number of subjects	113	109	222
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	52.1	49.2	
standard deviation	± 13.9	± 14.5	-
Gender categorical Units: Subjects			
Female	30	31	61
Male	83	78	161

End points

End points reporting groups

Reporting group title	Steroid avoidance

Reporting group description:

Induction with ATG (Thymoglobuline®; Sanofi AB) at 2.5 mg/kg peroperatively before perfusion at day 0, and day 1; methylprednisolone bolus (Solu-Medrol®; Pfizer) 250 mg before the first ATG dose and 50 mg before the second ATG dose, and maintenance treatment based on prolonged-release low-dose tacrolimus (Advagraf®; Astellas Pharma), starting dose 0.2 mg/kg once daily with target trough levels 5-10 ng/ml within first three months and thereafter 4-7 ng/ml, and MMF 1g twice a day controlled by a single area under the curve (AUC) measurement on day 10±5 with target AUC 40-60 mg*h/L.

Reporting group title	Steroid maintenance (standard of care)

Reporting group description:

Induction with basiliximab (Simulect®; Novartis) at 20 mg on day 0 and day 4; methylprednisolone 250-500 mg day 0 before reperfusion, according to the local center practice, and maintenance treatment as in SA-arm plus prednisolone in doses by local center practice, but not less than the final dose of 5 mg daily.

Primary: Efficacy

End point title	Efficacy[1]

End point description:

Incidence of NODAT as defined as any of the following, ≥2 FPG ≥7,0 mmol/l ≥ 30 days apart; 2-h Plasma Glucose ≥11,1 mmol/l in the OGTT≥ 30 days apart; Oral hypoglycemic ≥30 consecutive days; Insulin ≥30 consecutive days

End point type	Primary

End point timeframe:

12 months after transplantation

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 synopsis for more information.

End point values	Steroid avoidance	Steroid maintenance (standard of care)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	70[2]	97[3]		
Units: Individuals	12	16		

Notes:

[2] - PP 12m

[3] - PP 12m

Statistical analyses

No statistical analyses for this end point

Secondary: Safety - adverse events and serious adverse events

End point title	Safety - adverse events and serious adverse events

End point description:

Adverse events and serious adverse events including acute rejection and death, renal function.

End point type	Secondary

End point timeframe:
24 months after transplantation

End point values	Steroid avoidance	Steroid maintenance (standard of care)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	109		
Units: Number	73	69		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

12 months and 24 months.

Adverse event reporting additional description:

Please see summary report for more information.

Assessment type	Systematic

Dictionary used

Dictionary name	None
Dictionary version	0

Reporting groups

Reporting group title	Steroid avoidance

Reporting group description:

Induction with ATG (Thymoglobuline®; Sanofi AB) at 2.5 mg/kg peroperatively before perfusion at day 0, and day 1; methylprednisolone bolus (Solu-Medrol®; Pfizer) 250 mg before the first ATG dose and 50 mg before the second ATG dose, and maintenance treatment based on prolonged-release low-dose tacrolimus (Advagraf®; Astellas Pharma), starting dose 0.2 mg/kg once daily with target trough levels 5-10 ng/ml within first three months and thereafter 4-7 ng/ml, and MMF 1g twice a day controlled by a single area under the curve (AUC) measurement on day 10±5 with target AUC 40-60 mg*h/L.

Reporting group title	Steroid maintenance (standard of care)

Reporting group description:

Induction with basiliximab (Simulect®; Novartis) at 20 mg on day 0 and day 4; methylprednisolone 250-500 mg day 0 before reperfusion, according to the local center practice, and maintenance treatment as in SA-arm plus prednisolone in doses by local center practice, but not less than the final dose of 5 mg daily.

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: Please see synopsis for more information.

Serious adverse events	Steroid avoidance	Steroid maintenance (standard of care)	
Total subjects affected by serious adverse events			
subjects affected / exposed	73 / 113 (64.60%)	69 / 109 (63.30%)	
number of deaths (all causes)	1	3	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Pancreatic carcinoma			
subjects affected / exposed	1 / 113 (0.88%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			

Haematoma			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	1 / 113 (0.88%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphocele			
subjects affected / exposed	4 / 113 (3.54%)	2 / 109 (1.83%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phlebitis			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	2 / 113 (1.77%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Laparotomy			
subjects affected / exposed	1 / 113 (0.88%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrectomy			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parathyroidectomy			
subjects affected / exposed	2 / 113 (1.77%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urostomy			

subjects affected / exposed	1 / 113 (0.88%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 113 (0.88%)	0 / 109 (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	4 / 113 (3.54%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Biopsy liver			

subjects affected / exposed	1 / 113 (0.88%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatine increased			
subjects affected / exposed	1 / 113 (0.88%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	14 / 113 (12.39%)	15 / 109 (13.76%)	
occurrences causally related to treatment / all	0 / 20	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood urine			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
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			
Arteriovenous fistula site complication			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complications of transplanted kidney			
subjects affected / exposed	1 / 113 (0.88%)	3 / 109 (2.75%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft haemorrhage			
subjects affected / exposed	1 / 113 (0.88%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	2 / 113 (1.77%)	4 / 109 (3.67%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			

Cerebral infarction			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Convulsions local	Additional description: "Convulsion"		
subjects affected / exposed	1 / 113 (0.88%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis allergic			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 113 (0.88%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukopenia			
subjects affected / exposed	1 / 113 (0.88%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	3 / 113 (2.65%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 113 (0.88%)	2 / 109 (1.83%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Constipation			
subjects affected / exposed	1 / 113 (0.88%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	4 / 113 (3.54%)	5 / 109 (4.59%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	1 / 113 (0.88%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal pain			
subjects affected / exposed	1 / 113 (0.88%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-abdominal haemorrhage			
subjects affected / exposed	1 / 113 (0.88%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	1 / 113 (0.88%)	2 / 109 (1.83%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal perforation			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			

subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	5 / 113 (4.42%)	5 / 109 (4.59%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proteinuria			
subjects affected / exposed	1 / 113 (0.88%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal impairment			
subjects affected / exposed	0 / 113 (0.00%)	3 / 109 (2.75%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal vein thrombosis			
subjects affected / exposed	1 / 113 (0.88%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric stenosis			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	1 / 113 (0.88%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			

subjects affected / exposed	1 / 113 (0.88%)	4 / 109 (3.67%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	1 / 113 (0.88%)	0 / 109 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus colitis			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			

Dehydration			
subjects affected / exposed	0 / 113 (0.00%)	1 / 109 (0.92%)	
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	Steroid avoidance	Steroid maintenance (standard of care)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 113 (0.00%)	0 / 109 (0.00%)	

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Please see synopsis for all information. Complete appendices can be provided upon request.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/24959347