Clinical trial results:
Combined low-dose everolimus and low-dose tacrolimus after alemtuzumab induction therapy: a randomized prospective trial in lung transplantation

Summary

EudraCT number	2018-001680-24
Trial protocol	AT
Global end of trial date	23 May 2024

Results information

Result version number	v1 (current)
This version publication date	11 April 2026
First version publication date	11 April 2026

Trial information

Trial identification

Sponsor protocol code	ALiKE

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Waehringer Guertel 18-20, Vienna, Austria, 1090
Public contact	Medical University of Vienna, Division of Thoracic surgery, Medical University of Vienna, 0043 14040056400,
Scientific contact	Medical University of Vienna, Division of Thoracic surgery, Medical University of Vienna, 0043 14040056400,

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	17 December 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 May 2024
Global end of trial reached?	Yes
Global end of trial date	23 May 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

-Primary Objective
To analyze the effect of the combined use of low-dose everolimus and low-dose tacrolimus after alemtuzumab induction therapy on kidney function, measured as eGFR.

Protection of trial subjects:

The patients' study visits were sceduled as part of their regular transplant follow-up visits to the outpatient clinic

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 July 2018
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	Austria: 110
Worldwide total number of subjects	110
EEA total number of subjects	110

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)	85
From 65 to 84 years	25
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

bilateral lung transplantation,
age greater than 18 years,
no pre-transplant colonization of Burkholderia or resistant Mycobacterium abscessus

Pre-assignment

Screening details:

bilateral lung transplantation,
age greater than 18 years,
no pre-transplant colonization of Burkholderia or resistant Mycobacterium abscessus,
no inclusion in other studies,
complete healing of bronchial anastomosis at the time of randomization,
no wound infection at the time of randomization

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	control

Arm description:

Tacrolimus:
initial dose: no change compared to pre-randomization dose
target dose: the dose is adjusted according to target drug blood level (1st-3rd mo 4-5 ng/ml, 3rd-12th mo 3-4 ng/ml, 12th-24th mo 2.5 ng/ml)

Arm type	Active comparator
Investigational medicinal product name	tacrolimus
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

initial dose: no change compared to pre-randomization dose
target dose: the dose is adjusted according to target drug blood level (1st-3rd mo 4-5 ng/ml, 3rd-12th mo 3-4 ng/ml, 12th-24th mo 2.5 ng/ml)

Arm title	treatment

Arm description:

Everolimus:
initial dose: the standard dose of 75mg twice daily, adjusted according to body weight
target dose: the dose is adjusted according to target drug blood level (1st-3rd mo 4-5 ng/ml, 3rd-12th mo 3-4 ng/ml, 12th-24th mo 2.5 ng/ml)
Tacrolimus:
initial dose: half dose of pre-randomization dose
target dose: the dose is adjusted according to target drug blood level (1st-3rd mo 4-5 ng/ml, 3rd-12th mo 3-4 ng/ml, 12th-24th mo 2.5 ng/ml)

Arm type	Experimental

Investigational medicinal product name	everolimus
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

initial dose: the standard dose of 75mg twice daily, adjusted according to body weight
target dose: the dose is adjusted according to target drug blood level (1st-3rd mo 4-5 ng/ml, 3rd-12th mo 3-4 ng/ml, 12th-24th mo 2.5 ng/ml)

Investigational medicinal product name	tacrolimus
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

initial dose: half dose of pre-randomization dose
target dose: the dose is adjusted according to target drug blood level (1st-3rd mo 4-5 ng/ml, 3rd-12th mo 3-4 ng/ml, 12th-24th mo 2.5 ng/ml)

Number of subjects in period 1	control	treatment
Started	56	54
Completed	40	39
Not completed	16	15
Adverse event, serious fatal	9	4
regimen changed due to side effects	5	10
re-transplantation	2	1

Baseline characteristics

Reporting groups	
Reporting group title	control

Reporting group description:

Tacrolimus:
initial dose: no change compared to pre-randomization dose
target dose: the dose is adjusted according to target drug blood level (1st-3rd mo 4-5 ng/ml, 3rd-12th mo 3-4 ng/ml, 12th-24th mo 2.5 ng/ml)

Reporting group title	treatment

Reporting group description:

Everolimus:
initial dose: the standard dose of 75mg twice daily, adjusted according to body weight
target dose: the dose is adjusted according to target drug blood level (1st-3rd mo 4-5 ng/ml, 3rd-12th mo 3-4 ng/ml, 12th-24th mo 2.5 ng/ml)
Tacrolimus:
initial dose: half dose of pre-randomization dose
target dose: the dose is adjusted according to target drug blood level (1st-3rd mo 4-5 ng/ml, 3rd-12th mo 3-4 ng/ml, 12th-24th mo 2.5 ng/ml)

Reporting group values	control	treatment	Total
Number of subjects	56	54	110
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)	46	39	85
From 65-84 years	10	15	25
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	17	21	38
Male	39	33	72

End points

End points reporting groups

Reporting group title	control

Reporting group description:

Tacrolimus:
initial dose: no change compared to pre-randomization dose
target dose: the dose is adjusted according to target drug blood level (1st-3rd mo 4-5 ng/ml, 3rd-12th mo 3-4 ng/ml, 12th-24th mo 2.5 ng/ml)

Reporting group title	treatment

Reporting group description:

Everolimus:
initial dose: the standard dose of 75mg twice daily, adjusted according to body weight
target dose: the dose is adjusted according to target drug blood level (1st-3rd mo 4-5 ng/ml, 3rd-12th mo 3-4 ng/ml, 12th-24th mo 2.5 ng/ml)
Tacrolimus:
initial dose: half dose of pre-randomization dose
target dose: the dose is adjusted according to target drug blood level (1st-3rd mo 4-5 ng/ml, 3rd-12th mo 3-4 ng/ml, 12th-24th mo 2.5 ng/ml)

Primary: eGFR

End point title	eGFR

End point description:

End point type	Primary

End point timeframe:

24 months

End point values	control	treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	39		
Units: ml/min/1.73m²				
number (confidence interval 95%)	69 (61.9 to 76.1)	68.9 (61.1 to 76.8)		

Statistical analyses

Statistical analysis title	mixed-effects model for eGFR difference at 24 m
Comparison groups	control v treatment

Number of subjects included in analysis	79
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.475
Method	Mixed models analysis

Adverse events

Adverse events information	
Timeframe for reporting adverse events: from randomization to 24 months post tx	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	28

Reporting groups	
Reporting group title	control
Reporting group description: Tacrolimus: initial dose: no change compared to pre-randomization dose target dose: the dose is adjusted according to target drug blood level (1st-3rd mo 4-5 ng/ml, 3rd-12th mo 3-4 ng/ml, 12th-24th mo 2.5 ng/ml)	
Reporting group title	treatment
Reporting group description: Everolimus: initial dose: the standard dose of 75mg twice daily, adjusted according to body weight target dose: the dose is adjusted according to target drug blood level (1st-3rd mo 4-5 ng/ml, 3rd-12th mo 3-4 ng/ml, 12th-24th mo 2.5 ng/ml) Tacrolimus: initial dose: half dose of pre-randomization dose target dose: the dose is adjusted according to target drug blood level (1st-3rd mo 4-5 ng/ml, 3rd-12th mo 3-4 ng/ml, 12th-24th mo 2.5 ng/ml)	

Serious adverse events	control	treatment	
Total subjects affected by serious adverse events			
subjects affected / exposed	32 / 56 (57.14%)	26 / 54 (48.15%)	
number of deaths (all causes)	9	4	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vascular disorders			
Peripheral vascular disease			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			

subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Septum perforation closure			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pneumonia			
subjects affected / exposed	7 / 56 (12.50%)	4 / 54 (7.41%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	6 / 56 (10.71%)	2 / 54 (3.70%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 4	0 / 1	
Respiratory infection			
subjects affected / exposed	1 / 56 (1.79%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute allograft rejection			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute cellular rejection			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

ARDS			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aspiration pneumonia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bilateral pneumonia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic lung allograft dysfunction			
subjects affected / exposed	1 / 56 (1.79%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	1 / 56 (1.79%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnea			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza A H1N1 pneumonia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung transplant rejection			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Organizing pneumonia			

subjects affected / exposed	1 / 56 (1.79%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	2 / 56 (3.57%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory insufficiency			
subjects affected / exposed	4 / 56 (7.14%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Open wound			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orbital fracture			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative thoracic procedure complication			

subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Serial rib fracture			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	2 / 56 (3.57%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary vein isolation			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			

Cerebral abscess			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	2 / 56 (3.57%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Acute appendicitis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon perforation			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epigastric discomfort			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GI bleed			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sigmoid diverticulitis			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Stomatitis			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcerative gastritis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney failure			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Kidney stone			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Acute pancreatitis			

subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Ankle fracture			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis of knee			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	1 / 56 (1.79%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture L1			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (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			
Clostridium difficile infection			
subjects affected / exposed	1 / 56 (1.79%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CMV infection			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Empyema and pericarditis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Herpes zoster			
subjects affected / exposed	2 / 56 (3.57%)	2 / 54 (3.70%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory infection			
subjects affected / exposed	0 / 56 (0.00%)	3 / 54 (5.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
SARS-CoV-2 infection			
subjects affected / exposed	2 / 56 (3.57%)	2 / 54 (3.70%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	1 / 56 (1.79%)	1 / 54 (1.85%)	
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 / 56 (0.00%)	1 / 54 (1.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hyperglycemia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatremia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	
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: 5 %

Non-serious adverse events	control	treatment	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	44 / 56 (78.57%)	44 / 54 (81.48%)	
Investigations			
CRP increased			
subjects affected / exposed	12 / 56 (21.43%)	8 / 54 (14.81%)	
occurrences (all)	12	10	
Donor specific antibody present			
subjects affected / exposed	3 / 56 (5.36%)	4 / 54 (7.41%)	
occurrences (all)	3	4	
Lung function decreased			
subjects affected / exposed	6 / 56 (10.71%)	3 / 54 (5.56%)	
occurrences (all)	7	4	
Injury, poisoning and procedural complications			
Wound infection			
subjects affected / exposed	3 / 56 (5.36%)	5 / 54 (9.26%)	
occurrences (all)	3	5	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	4 / 56 (7.14%)	3 / 54 (5.56%)	
occurrences (all)	4	3	
General disorders and administration site conditions			
Edema			
subjects affected / exposed	5 / 56 (8.93%)	10 / 54 (18.52%)	
occurrences (all)	5	11	
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	6 / 56 (10.71%)	2 / 54 (3.70%)	
occurrences (all)	6	2	
Gastrointestinal disorders			
Dairrhea			
subjects affected / exposed	4 / 56 (7.14%)	7 / 54 (12.96%)	
occurrences (all)	5	9	
Gastroparesis			

subjects affected / exposed	4 / 56 (7.14%)	1 / 54 (1.85%)	
occurrences (all)	4	1	
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	3 / 56 (5.36%)	4 / 54 (7.41%)	
occurrences (all)	3	4	
Pneumonia			
subjects affected / exposed	4 / 56 (7.14%)	0 / 54 (0.00%)	
occurrences (all)	4	0	
Respiratory tract infection			
subjects affected / exposed	11 / 56 (19.64%)	5 / 54 (9.26%)	
occurrences (all)	17	5	
Respiratory tract infection bacterial			
subjects affected / exposed	5 / 56 (8.93%)	7 / 54 (12.96%)	
occurrences (all)	6	8	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	3 / 56 (5.36%)	0 / 54 (0.00%)	
occurrences (all)	3	0	
Infections and infestations			
Aspergillus infection			
subjects affected / exposed	4 / 56 (7.14%)	1 / 54 (1.85%)	
occurrences (all)	4	1	
CMV infection			
subjects affected / exposed	6 / 56 (10.71%)	3 / 54 (5.56%)	
occurrences (all)	7	3	
SARS-CoV-2 infection			
subjects affected / exposed	12 / 56 (21.43%)	12 / 54 (22.22%)	
occurrences (all)	13	12	
Fungal infection			
subjects affected / exposed	3 / 56 (5.36%)	1 / 54 (1.85%)	
occurrences (all)	3	1	
Herpes zoster			
subjects affected / exposed	0 / 56 (0.00%)	4 / 54 (7.41%)	
occurrences (all)	0	4	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 May 2020	Gene Expression Analysis was included

Notes:

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.

the non-double-blind design may have introduced bias

Notes: