Clinical trial results:
HIGH DOSE SUPPLEMENTATION OF SELENIUM IN LEFT VENTRICULAR ASSIST DEVICE (LVAD) IMPLANT SURGERY – A DOUBLE BLIND RANDOMISED CONTROLLED TRIAL

Summary

EudraCT number	2013-001357-26
Trial protocol	DE
Global end of trial date	07 September 2017

Results information

Result version number	v1 (current)
This version publication date	06 February 2022
First version publication date	06 February 2022

Trial information

Trial identification

Sponsor protocol code	13-036

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02530788
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Universitätsklinikum RWTH Aachen
Sponsor organisation address	Pauwelsstraße 30, Aachen, Germany, 52074
Public contact	Center for Translational & Clinical Research Aachen (CTC-A), University RWTH Aachen, 49 2418080092, ctc-a-spoqs@ukaachen.de
Scientific contact	Center for Translational & Clinical Research Aachen (CTC-A), University RWTH Aachen, 49 2418080092, ctc-a-spoqs@ukaachen.de

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	07 April 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 September 2017
Global end of trial reached?	Yes
Global end of trial date	07 September 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the effects and safety of Selenium supplementation on postoperative recovery after LVAD implant surgery.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonisation of Good Clinical Practice, the principles of the Declaration of Helsinki, as well as other applicable local ethical and legal requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 August 2015
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	Germany: 21
Worldwide total number of subjects	21
EEA total number of subjects	21

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)	11
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment and treatment of subjects was performed in one trial center. Overall 21 subjects were enrolled and randomized in the clinical trial in the timeframe from 25.08.2015 till 07.09.2017.

Pre-assignment

Screening details:

Overall 21 subjects were screened in one trial center. Of those 21 subjects screened, all 21 subjects met the inclusion and exclusion criteria and were enrolled and randomized in the clinical trial.

Period 1

Period 1 title	evening before surgery
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 1	Selenase	Placebo
Started	11	10
Completed	11	10

Period 2

Period 2 title	ICU release or post-operative day 30
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 2	Selenase	Placebo
Started	11	10
Completed	11	10

Period 3

Period 3 title	Post-operative day 7
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 3	Selenase	Placebo
Started	11	10
Completed	11	10

Period 4

Period 4 title	Post-operative day 28
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes

Arm title	Selenase
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once 300 µg orally on evening before surgery	
Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once 3000 µg intravenous bolusinfusion while surgery, daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)	
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once orally on evening before surgery	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once intravenous bolusinfusion while surgery, daily intranvenous bolusinfusion (maximum till post operative day 13)	

Number of subjects in period 4	Selenase	Placebo
Started	11	10
Completed	11	10

Period 5

Period 5 title	Day 0
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 5	Selenase	Placebo
Started	11	10
Completed	11	10

Period 6	
Period 6 title	Day 1
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms	
Are arms mutually exclusive?	Yes
Arm title	Selenase
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once 300 µg orally on evening before surgery	
Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once 3000 µg intravenous bolusinfusion while surgery, daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)	
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once orally on evening before surgery	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 6	Selenase	Placebo
Started	11	10
Completed	11	10

Period 7

Period 7 title	Day 2
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 7	Selenase	Placebo
Started	11	10
Completed	11	10

Period 8

Period 8 title	Day 3
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 8	Selenase	Placebo
Started	11	10
Completed	11	10

Period 9

Period 9 title	Day 4
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes

Arm title	Selenase
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once 300 µg orally on evening before surgery	
Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once 3000 µg intravenous bolusinfusion while surgery, daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)	
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once orally on evening before surgery	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once intravenous bolusinfusion while surgery, daily intranvenous bolusinfusion (maximum till post operative day 13)	

Number of subjects in period 9	Selenase	Placebo
Started	11	10
Completed	11	10

Period 10

Period 10 title	Day 5
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 10	Selenase	Placebo
Started	11	10
Completed	11	10

Period 11	
Period 11 title	Day 6
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator
Arms	
Are arms mutually exclusive?	Yes
Arm title	Selenase
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once 300 µg orally on evening before surgery	
Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once 3000 µg intravenous bolusinfusion while surgery, daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)	
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once orally on evening before surgery	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 11	Selenase	Placebo
Started	11	10
Completed	11	10

Period 12

Period 12 title	Day 7
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 12	Selenase	Placebo
Started	11	10
Completed	11	10

Period 13

Period 13 title	Day 8
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 13	Selenase	Placebo
Started	11	10
Completed	11	10

Period 14

Period 14 title	Day 9
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes

Arm title	Selenase
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once 300 µg orally on evening before surgery	
Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once 3000 µg intravenous bolusinfusion while surgery, daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)	
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once orally on evening before surgery	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once intravenous bolusinfusion while surgery, daily intranvenous bolusinfusion (maximum till post operative day 13)	

Number of subjects in period 14	Selenase	Placebo
Started	11	10
Completed	11	10

Period 15

Period 15 title	Day 10
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 15	Selenase	Placebo
Started	11	10
Completed	11	10

Period 16	
Period 16 title	Day 11
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator
Arms	
Are arms mutually exclusive?	Yes
Arm title	Selenase
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once 300 µg orally on evening before surgery	
Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once 3000 µg intravenous bolusinfusion while surgery, daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)	
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once orally on evening before surgery	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 16	Selenase	Placebo
Started	11	10
Completed	11	10

Period 17

Period 17 title	Day 12
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 17	Selenase	Placebo
Started	11	10
Completed	11	10

Period 18

Period 18 title	Day 13
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 18	Selenase	Placebo
Started	11	10
Completed	11	10

Period 19

Period 19 title	Day 14
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes

Arm title	Selenase
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once 300 µg orally on evening before surgery	
Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once 3000 µg intravenous bolusinfusion while surgery, daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)	
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once orally on evening before surgery	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once intravenous bolusinfusion while surgery, daily intranvenous bolusinfusion (maximum till post operative day 13)	

Number of subjects in period 19	Selenase	Placebo
Started	11	10
Completed	11	10

Period 20

Period 20 title	Day 15
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 20	Selenase	Placebo
Started	11	10
Completed	11	10

Period 21	
Period 21 title	Day 16
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator
Arms	
Are arms mutually exclusive?	Yes
Arm title	Selenase
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once 300 µg orally on evening before surgery	
Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once 3000 µg intravenous bolusinfusion while surgery, daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)	
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once orally on evening before surgery	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 21	Selenase	Placebo
Started	11	10
Completed	11	10

Period 22

Period 22 title	Day 17
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 22	Selenase	Placebo
Started	11	10
Completed	11	10

Period 23

Period 23 title	Day 18
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 23	Selenase	Placebo
Started	11	10
Completed	11	10

Period 24

Period 24 title	Day 19
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes

Arm title	Selenase
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once 300 µg orally on evening before surgery	
Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once 3000 µg intravenous bolusinfusion while surgery, daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)	
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once orally on evening before surgery	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once intravenous bolusinfusion while surgery, daily intranvenous bolusinfusion (maximum till post operative day 13)	

Number of subjects in period 24	Selenase	Placebo
Started	11	10
Completed	11	10

Period 25

Period 25 title	Day 20
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 25	Selenase	Placebo
Started	11	10
Completed	11	10

Period 26	
Period 26 title	Day 21
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator
Arms	
Are arms mutually exclusive?	Yes
Arm title	Selenase
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once 300 µg orally on evening before surgery	
Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once 3000 µg intravenous bolusinfusion while surgery, daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)	
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once orally on evening before surgery	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 26	Selenase	Placebo
Started	11	10
Completed	11	10

Period 27

Period 27 title	Day 22
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 27	Selenase	Placebo
Started	11	10
Completed	11	10

Period 28

Period 28 title	Day 23
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 28	Selenase	Placebo
Started	11	10
Completed	11	10

Period 29

Period 29 title	Day 24
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes

Arm title	Selenase
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once 300 µg orally on evening before surgery	
Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once 3000 µg intravenous bolusinfusion while surgery, daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)	
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once orally on evening before surgery	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once intravenous bolusinfusion while surgery, daily intranvenous bolusinfusion (maximum till post operative day 13)	

Number of subjects in period 29	Selenase	Placebo
Started	11	10
Completed	11	10

Period 30

Period 30 title	Day 25
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 30	Selenase	Placebo
Started	11	10
Completed	11	10

Period 31	
Period 31 title	Day 26
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator
Arms	
Are arms mutually exclusive?	Yes
Arm title	Selenase
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once 300 µg orally on evening before surgery	
Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once 3000 µg intravenous bolusinfusion while surgery, daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)	
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once orally on evening before surgery	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 31	Selenase	Placebo
Started	11	10
Completed	11	10

Period 32

Period 32 title	Day 27
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 32	Selenase	Placebo
Started	11	10
Completed	11	10

Period 33

Period 33 title	Day 28
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 33	Selenase	Placebo
Started	11	10
Completed	11	10

Period 34

Period 34 title	Day 29
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes

Arm title	Selenase
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once 300 µg orally on evening before surgery	
Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once 3000 µg intravenous bolusinfusion while surgery, daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)	
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: once orally on evening before surgery	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: once intravenous bolusinfusion while surgery, daily intranvenous bolusinfusion (maximum till post operative day 13)	

Number of subjects in period 34	Selenase	Placebo
Started	11	10
Completed	11	10

Period 35

Period 35 title	Day 30
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Selenase

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Selen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once 300 µg orally on evening before surgery

Investigational medicinal product name	selenase T pro injectione
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once 3000 µg intravenous bolusinfusion while surgery,
daily 1000 µg intravenous bolusinfusion post surgery (maximum till post operative day 13)

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

once orally on evening before surgery

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

once intravenous bolusinfusion while surgery,
daily intranvenous bolusinfusion (maximum till post operative day 13)

Number of subjects in period 35	Selenase	Placebo
Started	11	10
Completed	11	10

Baseline characteristics

Reporting groups	
Reporting group title	Selenase
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Reporting group values	Selenase	Placebo	Total
Number of subjects	11	10	21
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	63.82	61.5	
standard deviation	± 10.91	± 8.127	-
Gender categorical Units: Subjects			
Female	1	1	2
Male	10	9	19

End points

End points reporting groups

Reporting group title	Selenase
Reporting group description: -	
Reporting group title	Placebo
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Reporting group title	Placebo
Reporting group description: -	

Primary: Composite Outcome

End point title	Composite Outcome
End point description: ICU independency, independency of dialysis, circulatory support and ventilation	
End point type	Primary
End point timeframe: from surgery till ICU release or post-operative day 30	

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: days				
median (inter-quartile range (Q1-Q3))	214 (61 to 381)	117 (64 to 287)		

Statistical analyses

Statistical analysis title	Analysis composite outcome
Comparison groups	Selenase v Placebo
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.89
Method	Kruskal-wallis

Secondary: Mortality

End point title	Mortality

End point description:

End point type	Secondary

End point timeframe:

POD 28

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: subjects				
alive	9	9		
deceased	2	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Persistent Organ Disfunction

End point title	Persistent Organ Disfunction

End point description:

End point type	Secondary

End point timeframe:

POD 7

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: subjects				
yes	8	3		
no	3	7		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of nosocomial infections

End point title	Incidence of nosocomial infections

End point description:

End point type	Secondary

End point timeframe:

ICU release or POD 30

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: subjects				
yes	5	5		
no	6	5		

Statistical analyses

No statistical analyses for this end point

Secondary: Acute renal failure

End point title	Acute renal failure

End point description:

End point type	Secondary

End point timeframe:
ICU release or POD 30

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: subjects				
yes	3	0		
no	8	10		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of mechanical ventialtion

End point title	Duration of mechanical ventialtion

End point description:

End point type	Secondary

End point timeframe:
ICU release or POD 30

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: hours				
median (inter-quartile range (Q1-Q3))	91 (27 to 311)	89 (34 to 267)		

Statistical analyses

No statistical analyses for this end point

Secondary: Invasive mechanical ventilation

End point title	Invasive mechanical ventilation

End point description:

End point type	Secondary

End point timeframe:
ICU release or POD 30

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: subjects				
yes	7	7		
no	4	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of postoperative delirium

End point title	Incidence of postoperative delirium

End point description:

End point type	Secondary

End point timeframe:
ICU release or POD 30

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: subjects				
yes	3	1		
no	8	9		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of ICU stay

End point title	Duration of ICU stay

End point description:

End point type	Secondary

End point timeframe:
ICU release or POD 30

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: days				
median (inter-quartile range (Q1-Q3))	18 (13 to 31)	16 (13 to 21)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of hospital stay

End point title	Duration of hospital stay

End point description:

End point type	Secondary

End point timeframe:

ICU release or POD 30

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[1]	10		
Units: days				
median (inter-quartile range (Q1-Q3))	35 (28 to 47)	37 (20 to 46)		

Notes:

[1] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Barthel index

End point title	Barthel index

End point description:

Individual Quality of life

End point type	Secondary

End point timeframe:

ICU release or POD 30

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: none				
median (inter-quartile range (Q1-Q3))	65 (0 to 85)	88 (69 to 95)		

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 1

End point title	Bilirubin - Day 1

End point description:

End point type	Secondary

End point timeframe:

Day 1

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: mg / dl				
arithmetic mean (standard deviation)	0.7518 (± 0.3121)	0.7880 (± 0.5853)		

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 2

End point title	Bilirubin - Day 2

End point description:

End point type	Secondary

End point timeframe:

Day 2

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[2]	10		
Units: mg / dl				
arithmetic mean (standard deviation)	0.5489 (± 0.1990)	0.9680 (± 1.2054)		

Notes:

[2] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 3

End point title	Bilirubin - Day 3

End point description:

End point type	Secondary

End point timeframe:

Day 3

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[3]	10		
Units: mg / dl				
arithmetic mean (standard deviation)	0.5222 (± 0.2107)	1.183 (± 1.316)		

Notes:

[3] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 4

End point title	Bilirubin - Day 4

End point description:

End point type	Secondary

End point timeframe:

Day 4

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[4]	10		
Units: mg / dl				
arithmetic mean (standard deviation)	0.5778 (± 0.2538)	0.9780 (± 1.3872)		

Notes:

[4] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 5

End point title	Bilirubin - Day 5

End point description:

End point type	Secondary

End point timeframe:

Day 5

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[5]	10		
Units: mg / dl				
arithmetic mean (standard deviation)	0.4656 (± 0.1538)	1.016 (± 1.583)		

Notes:

[5] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 6

End point title	Bilirubin - Day 6

End point description:

End point type	Secondary

End point timeframe:

Day 6

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[6]	10		
Units: mg / dl				
arithmetic mean (standard deviation)	0.4278 (± 0.1796)	0.7810 (± 1.1563)		

Notes:

[6] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 7

End point title	Bilirubin - Day 7

End point description:

End point type	Secondary

End point timeframe:

Day 7

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[7]	9[8]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.4289 (± 0.1997)	0.7833 (± 1.2007)		

Notes:

[7] - 2 missing data

[8] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 8

End point title	Bilirubin - Day 8

End point description:

End point type	Secondary

End point timeframe:

Day 8

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[9]	9[10]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.3756 (± 0.1991)	0.6956 (± 0.9717)		

Notes:

[9] - 2 missing data

[10] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 9

End point title	Bilirubin - Day 9

End point description:

End point type	Secondary

End point timeframe:

Day 9

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7[11]	9[12]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.4171 (± 0.2127)	0.6822 (± 1.0344)		

Notes:

[11] - 4 missing data

[12] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 10

End point title	Bilirubin - Day 10

End point description:

End point type	Secondary

End point timeframe:

Day 10

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7[13]	9[14]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.530 (± 0.416)	0.6422 (± 0.8226)		

Notes:

[13] - 4 missing data

[14] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 11

End point title	Bilirubin - Day 11

End point description:

End point type	Secondary

End point timeframe:

Day 11

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7[15]	9[16]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.5343 (± 0.4257)	0.6011 (± 0.7194)		

Notes:

[15] - 4 missing data

[16] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 12

End point title	Bilirubin - Day 12

End point description:

End point type	Secondary

End point timeframe:

Day 12

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7[17]	9[18]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.4871 (± 0.2840)	0.5867 (± 0.7055)		

Notes:

[17] - 4 missing data

[18] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 13

End point title	Bilirubin - Day 13

End point description:

End point type	Secondary

End point timeframe:

Day 13

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7[19]	8[20]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.5329 (± 0.2749)	0.7175 (± 0.9034)		

Notes:

[19] - 4 missing data

[20] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 14

End point title	Bilirubin - Day 14

End point description:

End point type	Secondary

End point timeframe:

Day 14

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7[21]	7[22]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.6243 (± 0.2995)	0.7114 (± 0.9646)		

Notes:

[21] - 4 missing data

[22] - 3 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 15

End point title	Bilirubin - Day 15

End point description:

End point type	Secondary

End point timeframe:

Day 15

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7[23]	7[24]		
Units: mg / dl				
arithmetic mean (standard deviation)	1.019 (± 1.016)	0.7914 (± 1.0291)		

Notes:

[23] - 4 missing data

[24] - 3 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 16

End point title	Bilirubin - Day 16

End point description:

End point type	Secondary

End point timeframe:

Day 16

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[25]	6[26]		
Units: mg / dl				
arithmetic mean (standard deviation)	1.30 (± 1.3480)	0.8217 (± 1.0916)		

Notes:

[25] - 5 missing data

[26] - 4 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 17

End point title	Bilirubin - Day 17

End point description:

End point type	Secondary

End point timeframe:

Day 17

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4[27]	5[28]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.5850 (± 0.2625)	1.164 (± 1.686)		

Notes:

[27] - 7 missing data

[28] - 5 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 18

End point title	Bilirubin - Day 18

End point description:

End point type	Secondary

End point timeframe:

Day 18

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4[29]	5[30]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.4850 (± 0.1841)	1.052 (± 1.052)		

Notes:

[29] - 7 missing data

[30] - 5 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 19

End point title	Bilirubin - Day 19

End point description:

End point type	Secondary

End point timeframe:

Day 19

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4[31]	5[32]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.4350 (± 0.1237)	1.002 (± 1.367)		

Notes:

[31] - 7 missing data

[32] - 5 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 20

End point title	Bilirubin - Day 20

End point description:

End point type	Secondary

End point timeframe:

Day 20

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4[33]	5[34]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.420 (± 0.1086)	1.304 (± 1.996)		

Notes:

[33] - 7 missing data

[34] - 5 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 21

End point title	Bilirubin - Day 21

End point description:

End point type	Secondary

End point timeframe:

Day 21

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3[35]	4[36]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.4233 (± 0.1222)	1.337 (± 1.924)		

Notes:

[35] - 8 missing data

[36] - 6 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 22

End point title	Bilirubin - Day 22

End point description:

End point type	Secondary

End point timeframe:

Day 22

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[37]	3[38]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.490 (± 0.09899)	1.557 (± 1.838)		

Notes:

[37] - 9 missing data

[38] - 7 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 23

End point title	Bilirubin - Day 23

End point description:

End point type	Secondary

End point timeframe:

Day 23

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[39]	2[40]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.5850 (± 0.2051)	2.235 (± 2.227)		

Notes:

[39] - 9 missing data

[40] - 8 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 24

End point title	Bilirubin - Day 24

End point description:

End point type	Secondary

End point timeframe:

Day 24

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[41]	2[42]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.5750 (± 0.1344)	3.065 (± 3.429)		

Notes:

[41] - 9 missing data

[42] - 8 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 25

End point title	Bilirubin - Day 25

End point description:

End point type	Secondary

End point timeframe:

Day 25

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[43]	2[44]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.480 (± 0.2546)	2.80 (± 3.224)		

Notes:

[43] - 9 missing data

[44] - 8 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 26

End point title	Bilirubin - Day 26

End point description:

End point type	Secondary

End point timeframe:

Day 26

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[45]	2[46]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.530 (± 0.2687)	2.755 (± 3.062)		

Notes:

[45] - 9 missing data

[46] - 8 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 27

End point title	Bilirubin - Day 27

End point description:

End point type	Secondary

End point timeframe:

Day 27

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[47]	2[48]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.450 (± 0.01414)	3.515 (± 4.137)		

Notes:

[47] - 9 missing data

[48] - 8 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 28

End point title	Bilirubin - Day 28

End point description:

End point type	Secondary

End point timeframe:

Day 28

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[49]	2[50]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.390 (± 0.02828)	3.840 (± 4.624)		

Notes:

[49] - 9 missing data

[50] - 8 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 29

End point title	Bilirubin - Day 29

End point description:

End point type	Secondary

End point timeframe:

Day 29

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[51]	1[52]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.360 (± 0.02828)	0.64 (± 0)		

Notes:

[51] - 9 missing data

[52] - 9 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Bilirubin - Day 30

End point title	Bilirubin - Day 30

End point description:

End point type	Secondary

End point timeframe:

Day 30

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1[53]	0[54]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.32 (± 0)	()		

Notes:

[53] - 10 missing data

[54] - 10 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 1

End point title	Creatinine - Day 1

End point description:

End point type	Secondary

End point timeframe:

Day 1

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: mg / dl				
arithmetic mean (standard deviation)	1.6482 (± 0.6442)	1.3250 (± 0.3832)		

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 2

End point title	Creatinine - Day 2

End point description:

End point type	Secondary

End point timeframe:

Day 2

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[55]	10		
Units: mg / dl				
arithmetic mean (standard deviation)	1.6989 (± 0.9114)	1.2560 (± 0.3838)		

Notes:

[55] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 3

End point title	Creatinine - Day 3

End point description:

End point type	Secondary

End point timeframe:

Day 3

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[56]	10		
Units: mg / dl				
arithmetic mean (standard deviation)	1.6833 (± 0.9721)	1.2040 (± 0.3923)		

Notes:

[56] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 4

End point title	Creatinine - Day 4

End point description:

End point type	Secondary

End point timeframe:

Day 4

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[57]	10		
Units: mg / dl				
arithmetic mean (standard deviation)	1.4578 (± 0.7929)	1.1560 (± 0.3631)		

Notes:

[57] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 5

End point title	Creatinine - Day 5

End point description:

End point type	Secondary

End point timeframe:

Day 5

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[58]	10		
Units: mg / dl				
arithmetic mean (standard deviation)	1.3233 (± 0.5042)	1.1690 (± 0.4626)		

Notes:

[58] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 6

End point title	Creatinine - Day 6

End point description:

End point type	Secondary

End point timeframe:

Day 6

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[59]	10		
Units: mg / dl				
arithmetic mean (standard deviation)	1.2256 (± 0.4189)	1.0870 (± 0.4529)		

Notes:

[59] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 7

End point title	Creatinine - Day 7

End point description:

End point type	Secondary

End point timeframe:

Day 7

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[60]	10		
Units: mg / dl				
arithmetic mean (standard deviation)	1.1422 (± 0.3986)	0.9718 (± 0.4830)		

Notes:

[60] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 8

End point title	Creatinine - Day 8

End point description:

End point type	Secondary

End point timeframe:

Day 8

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[61]	9[62]		
Units: mg / dl				
arithmetic mean (standard deviation)	1.154 (± 0.419)	1.0144 (± 0.3776)		

Notes:

[61] - 2 missing data

[62] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 9

End point title	Creatinine - Day 9

End point description:

End point type	Secondary

End point timeframe:

Day 9

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7[63]	9[64]		
Units: mg / dl				
arithmetic mean (standard deviation)	1.3357 (± 0.4266)	1.0122 (± 0.3502)		

Notes:

[63] - 4 missing data

[64] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 10

End point title	Creatinine - Day 10

End point description:

End point type	Secondary

End point timeframe:

Day 10

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7[65]	9[66]		
Units: mg / dl				
arithmetic mean (standard deviation)	1.3414 (± 0.5286)	1.0056 (± 0.3371)		

Notes:

[65] - 4 missing data

[66] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 11

End point title	Creatinine - Day 11

End point description:

End point type	Secondary

End point timeframe:

Day 11

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8[67]	10		
Units: mg / dl				
arithmetic mean (standard deviation)	1.3050 (± 0.4248)	1.0350 (± 0.3655)		

Notes:

[67] - 3 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 12

End point title	Creatinine - Day 12

End point description:

End point type	Secondary

End point timeframe:

Day 12

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7[68]	9[69]		
Units: mg / dl				
arithmetic mean (standard deviation)	1.430 (± 0.6019)	1.0144 (± 0.3259)		

Notes:

[68] - 4 missing data

[69] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 13

End point title	Creatinine - Day 13

End point description:

End point type	Secondary

End point timeframe:

Day 13

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7[70]	8[71]		
Units: mg / dl				
arithmetic mean (standard deviation)	1.4429 (± 0.7067)	0.9062 (± 0.2370)		

Notes:

[70] - 4 missing data

[71] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 14

End point title	Creatinine - Day 14

End point description:

End point type	Secondary

End point timeframe:

Day 14

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7[72]	8[73]		
Units: mg / dl				
arithmetic mean (standard deviation)	1.4486 (± 0.6592)	1.0962 (± 0.2752)		

Notes:

[72] - 4 missing data

[73] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 15

End point title	Creatinine - Day 15

End point description:

End point type	Secondary

End point timeframe:

Day 15

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7[74]	7[75]		
Units: mg / dl				
arithmetic mean (standard deviation)	1.4114 (± 0.8095)	1.1586 (± 0.3938)		

Notes:

[74] - 4 missing data

[75] - 3 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 16

End point title	Creatinine - Day 16

End point description:

End point type	Secondary

End point timeframe:

Day 16

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[76]	7[77]		
Units: mg / dl				
arithmetic mean (standard deviation)	1.5083 (± 0.6632)	1.1771 (± 0.4342)		

Notes:

[76] - 5 missing data

[77] - 3 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 17

End point title	Creatinine - Day 17

End point description:

End point type	Secondary

End point timeframe:

Day 17

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4[78]	5[79]		
Units: mg / dl				
arithmetic mean (standard deviation)	1.3450 (± 0.3423)	1.3940 (± 0.6742)		

Notes:

[78] - 7 missing data

[79] - 5 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 18

End point title	Creatinine - Day 18

End point description:

End point type	Secondary

End point timeframe:

Day 18

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4[80]	5[81]		
Units: mg / dl				
arithmetic mean (standard deviation)	1.220 (± 0.3753)	1.3460 (± 0.7241)		

Notes:

[80] - 7 missing data

[81] - 5 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 19

End point title	Creatinine - Day 19

End point description:

End point type	Secondary

End point timeframe:

Day 19

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4[82]	5[83]		
Units: mg / dl				
arithmetic mean (standard deviation)	1.0575 (± 0.260)	1.2820 (± 0.5681)		

Notes:

[82] - 7 missing data

[83] - 5 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 20

End point title	Creatinine - Day 20

End point description:

End point type	Secondary

End point timeframe:

Day 20

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4[84]	5[85]		
Units: mg / dl				
arithmetic mean (standard deviation)	1.080 (± 0.3383)	1.3580 (± 0.6242)		

Notes:

[84] - 7 missing data

[85] - 5 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 21

End point title	Creatinine - Day 21

End point description:

End point type	Secondary

End point timeframe:

Day 21

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3[86]	4[87]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.940 (± 0.2646)	1.425 (± 0.622)		

Notes:

[86] - 8 missing data

[87] - 6 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 22

End point title	Creatinine - Day 22

End point description:

End point type	Secondary

End point timeframe:

Day 22

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[88]	3[89]		
Units: mg / dl				
arithmetic mean (standard deviation)	1.070 (± 0.3818)	1.420 (± 0.3904)		

Notes:

[88] - 9 missing data

[89] - 7 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 23

End point title	Creatinine - Day 23

End point description:

End point type	Secondary

End point timeframe:

Day 23

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[90]	2[91]		
Units: mg / dl				
arithmetic mean (standard deviation)	1.170 (± 0.3111)	1.330 (± 0.2546)		

Notes:

[90] - 9 missing data

[91] - 8 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 24

End point title	Creatinine - Day 24

End point description:

End point type	Secondary

End point timeframe:

Day 24

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[92]	2[93]		
Units: mg / dl				
arithmetic mean (standard deviation)	1.090 (± 0.1273)	1.20 (± 0.01414)		

Notes:

[92] - 9 missing data

[93] - 8 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 25

End point title	Creatinine - Day 25

End point description:

End point type	Secondary

End point timeframe:

Day 25

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[94]	2[95]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.870 (± 0.1838)	1.0450 (± 0.1344)		

Notes:

[94] - 9 missing data

[95] - 8 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 26

End point title	Creatinine - Day 26

End point description:

End point type	Secondary

End point timeframe:

Day 26

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[96]	2[97]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.8450 (± 0.2616)	1.0350 (± 0.1909)		

Notes:

[96] - 9 missing data

[97] - 8 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 27

End point title	Creatinine - Day 27

End point description:

End point type	Secondary

End point timeframe:

Day 27

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[98]	2[99]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.810 (± 0.4525)	0.960 (± 0.09899)		

Notes:

[98] - 9 missing data

[99] - 8 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 28

End point title	Creatinine - Day 28

End point description:

End point type	Secondary

End point timeframe:

Day 28

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[100]	2[101]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.7750 (± 0.3041)	0.910 (± 0.07071)		

Notes:

[100] - 9 missing data

[101] - 8 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 29

End point title	Creatinine - Day 29

End point description:

End point type	Secondary

End point timeframe:

Day 29

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[102]	1[103]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.730 (± 0.2828)	0.96 (± 0)		

Notes:

[102] - 9 missing data

[103] - 9 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Creatinine - Day 30

End point title	Creatinine - Day 30

End point description:

End point type	Secondary

End point timeframe:

Day 30

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[104]	1[105]		
Units: mg / dl				
arithmetic mean (standard deviation)	0.630 (± 0.08485)	0.92 (± 0)		

Notes:

[104] - 9 missing data

[105] - 9 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: IL-6 - Baseline

End point title	IL-6 - Baseline

End point description:

End point type	Secondary

End point timeframe:

Baseline

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[106]	10		
Units: pg / ml				
arithmetic mean (standard deviation)	31.910 (± 82.533)	7.288 (± 10.605)		

Notes:

[106] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: IL-6 - Day 0

End point title	IL-6 - Day 0

End point description:

End point type	Secondary

End point timeframe:

Day 0

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[107]	10		
Units: pg / ml				
arithmetic mean (standard deviation)	365.526 (± 396.512)	248.678 (± 212.787)		

Notes:

[107] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: IL-6 - Day 1

End point title	IL-6 - Day 1

End point description:

End point type	Secondary

End point timeframe:

Day 1

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[108]	10		
Units: pg / ml				
arithmetic mean (standard deviation)	156.035 (± 91.049)	191.948 (± 139.490)		

Notes:

[108] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: IL-6 - Day 3

End point title	IL-6 - Day 3

End point description:

End point type	Secondary

End point timeframe:

Day 3

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[109]	10		
Units: pg / ml				
arithmetic mean (standard deviation)	115.276 (± 84.364)	148.111 (± 165.305)		

Notes:

[109] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: IL-6 - Day 5

End point title	IL-6 - Day 5

End point description:

End point type	Secondary

End point timeframe:

Day 5

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[110]	9[111]		
Units: pg / ml				
arithmetic mean (standard deviation)	68.465 (± 67.037)	56.891 (± 34.977)		

Notes:

[110] - 2 missing data

[111] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: IL-6 - Day 7

End point title	IL-6 - Day 7

End point description:

End point type	Secondary

End point timeframe:

Day 7

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[112]	9[113]		
Units: pg / ml				
arithmetic mean (standard deviation)	50.986 (± 34.452)	88.696 (± 44.160)		

Notes:

[112] - 2 missing data

[113] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: IL-6 - Day 13

End point title	IL-6 - Day 13

End point description:

End point type	Secondary

End point timeframe:

Day 13

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6[114]	9[115]		
Units: pg / ml				
arithmetic mean (standard deviation)	71.276 (± 104.124)	153.193 (± 257.173)		

Notes:

[114] - 5 missing data

[115] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Selenium - Baseline

End point title	Selenium - Baseline

End point description:

End point type	Secondary

End point timeframe:

Baseline

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[116]	10		
Units: µg / l				
arithmetic mean (standard deviation)	64.007 (± 16.523)	63.509 (± 11.875)		

Notes:

[116] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Selenium - Day 0

End point title	Selenium - Day 0

End point description:

End point type	Secondary

End point timeframe:

Day 0

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[117]	10		
Units: µg / l				
arithmetic mean (standard deviation)	144.553 (± 42.835)	49.010 (± 9.833)		

Notes:

[117] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Selenium - Day 1

End point title	Selenium - Day 1

End point description:

End point type	Secondary

End point timeframe:

Day 1

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10[118]	10		
Units: µg / l				
arithmetic mean (standard deviation)	102.397 (± 22.718)	44.913 (± 7.981)		

Notes:

[118] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Selenium - Day 3

End point title	Selenium - Day 3

End point description:

End point type	Secondary

End point timeframe:

Day 3

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[119]	10		
Units: µg / l				
arithmetic mean (standard deviation)	100.406 (± 24.496)	43.607 (± 11.135)		

Notes:

[119] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Selenium - Day 5

End point title	Selenium - Day 5

End point description:

End point type	Secondary

End point timeframe:

Day 5

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[120]	9[121]		
Units: µg / l				
arithmetic mean (standard deviation)	114.742 (± 20.977)	48.484 (± 13.328)		

Notes:

[120] - 2 missing data

[121] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Selenium - Day 7

End point title	Selenium - Day 7

End point description:

End point type	Secondary

End point timeframe:

Day 7

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9[122]	9[123]		
Units: µg / l				
arithmetic mean (standard deviation)	118.248 (± 17.170)	44.433 (± 7.982)		

Notes:

[122] - 2 missing data

[123] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Secondary: Selenium - Day 13

End point title	Selenium - Day 13

End point description:

End point type	Secondary

End point timeframe:

Day 13

End point values	Selenase	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5[124]	9[125]		
Units: µg / l				
arithmetic mean (standard deviation)	130.978 (± 26.623)	47.977 (± 11.133)		

Notes:

[124] - 6 missing data

[125] - 1 missing data

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 14 days (day before surgery till ICU release or POD 13)	
Assessment type	Systematic

Dictionary used	
Dictionary name	none
Dictionary version	0

Reporting groups	
Reporting group title	Selenase
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	Selenase	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 11 (63.64%)	3 / 10 (30.00%)	
number of deaths (all causes)	2	2	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
Cardiac decompensation			
subjects affected / exposed	0 / 11 (0.00%)	1 / 10 (10.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medial infarct			
subjects affected / exposed	0 / 11 (0.00%)	1 / 10 (10.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	2 / 11 (18.18%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pericardial tamponade			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute cardiopulmonary decompensation			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Circulatory failure			
subjects affected / exposed	0 / 11 (0.00%)	2 / 10 (20.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Hypertensive crisis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (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			
Hemiparesis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (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			
Re-intubation			

subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 11 (0.00%)	1 / 10 (10.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (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			
Renal failure			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (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			
Driveline infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (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: 0 %

Non-serious adverse events	Selenase	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 11 (72.73%)	6 / 10 (60.00%)	
Vascular disorders			
Hemorrhage			
subjects affected / exposed	3 / 11 (27.27%)	1 / 10 (10.00%)	
occurrences (all)	4	1	
Epistaxis			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Cardiac disorders			

Ventricular tachycardia			
subjects affected / exposed	1 / 11 (9.09%)	2 / 10 (20.00%)	
occurrences (all)	1	3	
Tachyarrhythmia absoluta			
subjects affected / exposed	3 / 11 (27.27%)	3 / 10 (30.00%)	
occurrences (all)	3	3	
Cardiac arrhythmia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Right heart failure			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Pericardial effusion			
subjects affected / exposed	2 / 11 (18.18%)	1 / 10 (10.00%)	
occurrences (all)	2	1	
Nervous system disorders			
Delirium			
subjects affected / exposed	2 / 11 (18.18%)	2 / 10 (20.00%)	
occurrences (all)	2	2	
Seizure			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Thrombocytopenia type II			
subjects affected / exposed	0 / 11 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Eye disorders			
Flickering before the eye			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Paralytic ileus			
subjects affected / exposed	0 / 11 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	

Gastritis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Tarry stool			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	3 / 11 (27.27%)	2 / 10 (20.00%)	
occurrences (all)	3	2	
Prolonged weaning			
subjects affected / exposed	2 / 11 (18.18%)	1 / 10 (10.00%)	
occurrences (all)	2	1	
Respiratory insufficiency			
subjects affected / exposed	2 / 11 (18.18%)	1 / 10 (10.00%)	
occurrences (all)	2	1	
Skin and subcutaneous tissue disorders			
Sternal wound healing disorder			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	3 / 11 (27.27%)	1 / 10 (10.00%)	
occurrences (all)	3	1	
Urosepsis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
Renal insufficiency			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			

Critical illness myopathy / Critical illness polyneuropathy			
subjects affected / exposed	2 / 11 (18.18%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	3 / 11 (27.27%)	3 / 10 (30.00%)	
occurrences (all)	4	3	
Sepsis			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Septic shock			
subjects affected / exposed	2 / 11 (18.18%)	1 / 10 (10.00%)	
occurrences (all)	2	1	
Driveline infection			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 10 (10.00%)	
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