Clinical trial results:
A Randomized, Open-Label, Multi-Centre, Phase 2a Study to Evaluate the Safety and Effect of STC3141 Continuous Infusion in Subjects with Severe COVID-19 Pneumonia

Summary

EudraCT number	2021-000399-12
Trial protocol	BE PL
Global end of trial date	07 January 2022

Results information

Result version number	v1
This version publication date	15 December 2022
First version publication date	15 December 2022

Trial information

Trial identification

Sponsor protocol code	GPHIP-0202

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04880694
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Grand Medical Pty Ltd
Sponsor organisation address	Shop 6 / 207 Pacific Highway , St Leonards, Australia, 2065
Public contact	Project Manager, Grand Medical Pty Ltd, zhouye@grandpharma.cn
Scientific contact	Chief Scientific Officer, Grand Medical Pty Ltd, jpang@grandpharma.cn

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 January 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 January 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to evaluate the safety of STC3141 in subjects with severe COVID-19 pneumonia

Protection of trial subjects:

All subjects randomized to the three cohorts received the same Standard of Care (SoC) treatment, whether treated with STC3141 or not.

Background therapy:

Standard of Care treatment per the Sciensano guidelines current at the time of the trial

Evidence for comparator: -

Actual start date of recruitment	04 May 2021
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	Belgium: 26
Worldwide total number of subjects	26
EEA total number of subjects	26

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)	23
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 26 subjects were screened. 25 subjects were randomized to study treatment.

Pre-assignment

Screening details:

A total of 26 subjects were screened. One screening failure due to exclusion criterion not met.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	STC3141 (58.3 mg/hr) + SoC

Arm description: -

Arm type	Experimental
Investigational medicinal product name	STC3141
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion

Dosage and administration details:

4,200 mg (58.3 mg/h for 72h)

Arm title	STC3141 (87.5 mg/hr) + SoC

Arm description:

IMP 87.5mg/hr for 72h and SoC treatment

Arm type	Experimental
Investigational medicinal product name	STC3141
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Infusion

Dosage and administration details:

6,300 mg (87.5mg/h for 72h)

Arm title	standard of care (SoC)

Arm description: -

Arm type	standard of care

No investigational medicinal product assigned in this arm

Number of subjects in period 1[1]	STC3141 (58.3 mg/hr) + SoC	STC3141 (87.5 mg/hr) + SoC	standard of care (SoC)
Started	10	10	5
Completed	10	10	5

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 26 signed informed consent, however, 1 subject was a screen failure and was excluded from randomization. Therefore, the number of randomized subjects does not equal the baseline number.

Baseline characteristics

Reporting groups	
Reporting group title	STC3141 (58.3 mg/hr) + SoC
Reporting group description: -	
Reporting group title	STC3141 (87.5 mg/hr) + SoC
Reporting group description:	
IMP 87.5mg/hr for 72h and SoC treatment	
Reporting group title	standard of care (SoC)
Reporting group description: -	

Reporting group values	STC3141 (58.3 mg/hr) + SoC	STC3141 (87.5 mg/hr) + SoC	standard of care (SoC)
Number of subjects	10	10	5
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	10	8	4
From 65-84 years	0	2	1
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	5	4	1
Male	5	6	4

Reporting group values	Total		
Number of subjects	25		
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)	22		
From 65-84 years	3		
85 years and over	0		
Gender categorical Units: Subjects			
Female	10		
Male	15		

End points

End points reporting groups

Reporting group title	STC3141 (58.3 mg/hr) + SoC
Reporting group description: -	
Reporting group title	STC3141 (87.5 mg/hr) + SoC
Reporting group description:	
IMP 87.5mg/hr for 72h and SoC treatment	
Reporting group title	standard of care (SoC)
Reporting group description: -	

Primary: Incidence of adverse events (AEs) up tp Day 30

End point title	Incidence of adverse events (AEs) up tp Day 30[1]
End point description:	

End point type	Primary
End point timeframe:	
From the time of informed consent until Day 30.	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Analysis was only descriptive, no further statistical analysis has been done

End point values	STC3141 (58.3 mg/hr) + SoC	STC3141 (87.5 mg/hr) + SoC	standard of care (SoC)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	5	
Units: events	13	41	7	

Statistical analyses

No statistical analyses for this end point

Primary: Incidence of treatment emergent adverse events (TEAEs) up to Day 30

End point title	Incidence of treatment emergent adverse events (TEAEs) up to Day 30[2]
End point description:	

End point type	Primary
End point timeframe:	
From the time of informed consent until Day 30.	

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Analysis was only descriptive, no further statistical analysis has been done

End point values	STC3141 (58.3 mg/hr) + SoC	STC3141 (87.5 mg/hr) + SoC	standard of care (SoC)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	5	
Units: events	13	37	7	

Statistical analyses

No statistical analyses for this end point

Primary: Incidence of serious adverse events (SAEs) up to Day 30

End point title	Incidence of serious adverse events (SAEs) up to Day 30[3]

End point description:

End point type	Primary

End point timeframe:

from the time of informed consent until Day 30.

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Analysis was only descriptive, no further statistical analysis has been done

End point values	STC3141 (58.3 mg/hr) + SoC	STC3141 (87.5 mg/hr) + SoC	standard of care (SoC)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	5	
Units: events	1	7	1	

Statistical analyses

No statistical analyses for this end point

Primary: Incidence of adverse events of special interest (AESIs) up to Day 30

End point title	Incidence of adverse events of special interest (AESIs) up to Day 30[4]

End point description:

End point type	Primary

End point timeframe:

From the time of informed consent until Day 30.

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Analysis was only descriptive, no further statistical analysis has been done

End point values	STC3141 (58.3 mg/hr) + SoC	STC3141 (87.5 mg/hr) + SoC	standard of care (SoC)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	5	
Units: events	0	0	0	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events should be collected from the time of informed consent until Day 30.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24

Reporting groups

Reporting group title	STC3141 (58.3 mg/hr) + SoC
Reporting group description: -	
Reporting group title	STC3141 (87.5 mg/hr) + SoC
Reporting group description: -	
Reporting group title	Standard of Care

Reporting group description: -

Serious adverse events	STC3141 (58.3 mg/hr) + SoC	STC3141 (87.5 mg/hr) + SoC	Standard of Care
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 10 (10.00%)	5 / 10 (50.00%)	1 / 5 (20.00%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events			0
Nervous system disorders			
Quadriparesis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Sudden death			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory, thoracic and mediastinal disorders			
Respiratory failure			
subjects affected / exposed	1 / 10 (10.00%)	2 / 10 (20.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			

subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia bacterial			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0.05 %

Non-serious adverse events	STC3141 (58.3 mg/hr) + SoC	STC3141 (87.5 mg/hr) + SoC	Standard of Care
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 10 (50.00%)	9 / 10 (90.00%)	2 / 5 (40.00%)
Cardiac disorders			
Bradycardia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 10 (0.00%)	2 / 10 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	3 / 10 (30.00%)	3 / 10 (30.00%)	1 / 5 (20.00%)
occurrences (all)	3	3	1
Vomiting			

subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	2	1	0
Diarrhoea			
subjects affected / exposed	0 / 10 (0.00%)	2 / 10 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	1 / 10 (10.00%)	2 / 10 (20.00%)	1 / 5 (20.00%)
occurrences (all)	1	2	1
Hypokalaemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 July 2021	Amendment to facilitate subject recruitment and to clarify questions/issues discovered during inclusion of the first subjects; recommended by the FAGG to alter exclusion criteria n1

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported