



Clinical trial results:

A single center, randomized, open-label, cross-over exploratory study to evaluate the pharmacodynamic and pharmacokinetic response to a subcutaneous administration or oral administration of furosemide in subjects presenting with chronic fluid overload

Summary

EudraCT number	2014-002546-49
Trial protocol	NL
Global end of trial date	08 April 2015

Results information

Result version number	v1 (current)
This version publication date	20 March 2023
First version publication date	20 March 2023
Summary attachment (see zip file)	SCP-01-001 Synopsis Report (SC_Pharmaceuticals_SCP_01_001_Synopsis_21Mar2017_final.pdf)

Trial information

Trial identification

Sponsor protocol code	SCP-01-001
-----------------------	------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02350725
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	scPharmaceuticals, Inc.
Sponsor organisation address	2400 District Ave, Suite 310, Burlington, MA, United States, 01803
Public contact	John Mohr, Pharm.D., FIDP, scPharmaceuticals, Inc., +1 (781) 301-722, jmohr@scpharma.com
Scientific contact	John Mohr, Pharm.D., FIDP, scPharmaceuticals, Inc., +1 (781) 301-7220, jmohr@scpharma.com

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	08 April 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 April 2015
Global end of trial reached?	Yes
Global end of trial date	08 April 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the effects of 80 mg of furosemide delivered by subcutaneous delivery in the abdominal area over 5 hours when compared to oral administration in patients with heart failure with chronic fluid overload.

Protection of trial subjects:

This trial was conducted in compliance with ICH Good Clinical Practice guidelines and was approved by the relevant Institutional Review Board. An Informed Consent was collected from all the subjects in this study and their safety was monitored until the conclusion of the subject's participation.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	4

From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was planned to enroll up to 10 subjects. Subsequently, 10 subjects were enrolled, all 10 subjects completed the study, and all 10 subjects were evaluable.

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	10
Number of subjects completed	10

Period 1

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

Arms

Are arms mutually exclusive?	No
------------------------------	----

Arm title	Subcutaneous
------------------	--------------

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Furosemide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

80 mg scFurosemide (8mg/mL) administered abdominally via standard s.c. infusion set with the use of a commercial infusion pump, over 5 hours (30mg in first hour followed by 12.5mg/hour over 4 hours)

Arm title	Oral
------------------	------

Arm description: -

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

Dosage and administration details:

oral furosemide (80 mg tablet)

Number of subjects in period 1	Subcutaneous	Oral
Started	10	10
Completed	10	10

Baseline characteristics

Reporting groups

Reporting group title	Period 1
-----------------------	----------

Reporting group description: -

Reporting group values	Period 1	Total	
Number of subjects	10	10	
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	69.9		
standard deviation	± 8.6	-	
Gender categorical			
Units: Subjects			
Female	2	2	
Male	8	8	
NYHA Class			
Units: Subjects			
Class I	0	0	
Class II	10	10	
Class III	0	0	
Class IV	0	0	
History of ischemic heart disease			
Units: Subjects			
Yes	6	6	
No	4	4	
BMI			
Units: Kg/m ²			
arithmetic mean	27.5		
standard deviation	± 4.5	-	

End points

End points reporting groups

Reporting group title	Subcutaneous
Reporting group description: -	
Reporting group title	Oral
Reporting group description: -	

Primary: Furosemide Plasma Concentration

End point title	Furosemide Plasma Concentration ^[1]
End point description:	

End point type	Primary
End point timeframe:	
30 Minutes after administration	

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: The study was not powered to analyze for a statistically significant difference between the groups. Hence a statistical analysis was not performed.

End point values	Subcutaneous	Oral		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: nanogram(s)/millilitre				
arithmetic mean (standard deviation)	916 (\pm 302)	1745 (\pm 1227)		

Statistical analyses

No statistical analyses for this end point

Primary: Furosemide Plasma Concentration

End point title	Furosemide Plasma Concentration ^[2]
End point description:	

End point type	Primary
End point timeframe:	
60 minutes after administration	

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: The study was not powered to analyze for a statistically significant difference between the groups. Hence a statistical analysis was not performed.

End point values	Subcutaneous	Oral		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: nanogram(s)/millilitre				
arithmetic mean (standard deviation)	2129 (± 445)	2620 (± 1346)		

Statistical analyses

No statistical analyses for this end point

Primary: Plasma Concentration over 1000 ng/ml

End point title	Plasma Concentration over 1000 ng/ml ^[3]
-----------------	---

End point description:

End point type	Primary
----------------	---------

End point timeframe:

Hours 2 - 5

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: The study was not powered to analyze for a statistically significant difference between the groups. Hence a statistical analysis was not performed.

End point values	Subcutaneous	Oral		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: Subjects	10	1		

Statistical analyses

No statistical analyses for this end point

Primary: Bioavailability

End point title	Bioavailability ^[4]
-----------------	--------------------------------

End point description:

End point type	Primary
----------------	---------

End point timeframe:

8 Hours after administration

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: The study was not powered to analyze for a statistically significant difference between the groups. Hence a statistical analysis was not performed.

End point values	Subcutaneous	Oral		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: percent				
number (not applicable)	99.6	61		

Statistical analyses

No statistical analyses for this end point

Primary: Urine Output

End point title	Urine Output ^[5]
-----------------	-----------------------------

End point description:

End point type	Primary
----------------	---------

End point timeframe:

8 hours

Notes:

[5] - 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: The study was not powered to analyze for a statistically significant difference between the groups. Hence a statistical analysis was not performed.

End point values	Subcutaneous	Oral		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: millilitre(s)				
arithmetic mean (full range (min-max))	1833 (1623 to 2726)	1550 (1353 to 1866)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Screening to Study Completion

Assessment type	Non-systematic
-----------------	----------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	19.0
--------------------	------

Reporting groups

Reporting group title	Subcutaneous
-----------------------	--------------

Reporting group description: -

Reporting group title	Oral
-----------------------	------

Reporting group description: -

Serious adverse events	Subcutaneous	Oral	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Subcutaneous	Oral	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 10 (60.00%)	0 / 10 (0.00%)	
Vascular disorders			
Stroke			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Bruise at Injection Site			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Exhausted			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	

Red discharge subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 10 (0.00%) 0	
Gastrointestinal disorders Burning/stinging sensation at/around injection site subjects affected / exposed occurrences (all)	4 / 10 (40.00%) 4	0 / 10 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders Exacerbated COPD subjects affected / exposed occurrences (all) Bronchitis subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1 1 / 10 (10.00%) 1	0 / 10 (0.00%) 0 0 / 10 (0.00%) 0	
Musculoskeletal and connective tissue disorders Cramps both legs subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 10 (0.00%) 0	
Infections and infestations Flu subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 10 (0.00%) 0	

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

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/30062191>