Clinical trial results:
Pilot study with St. Gero for heartburn

Summary

EudraCT number	2013-001584-22
Trial protocol	DE
Global end of trial date	28 August 2014

Results information

Result version number	v1 (current)
This version publication date	22 May 2020
First version publication date	22 May 2020
Summary attachment (see zip file)	2013-001584-22_Summary (VDM-032711_Summary.pdf)

Trial information

Trial identification

Sponsor protocol code	VDM/032711

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Gerolsteiner Brunnen GmbH & Co. KG
Sponsor organisation address	Vulkanring, Gerolstein, Germany,
Public contact	Leiter Techn. Entw. u. Ressourcen, Gerolsteiner Brunnen GmbH & Co. KG, 0049 659114423, drthomas.hens@gerolsteiner.com
Scientific contact	Leiter Techn. Entw. u. Ressourcen, Gerolsteiner Brunnen GmbH & Co. KG, 0049 659114423, drthomas.hens@gerolsteiner.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	23 June 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 August 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Investigation of the efficacy and tolerability of St. Gero in the pre / post comparison.

Efficacy parameters:
-Therapeutic course based on the questionnaire data (questionnaires "Reflux Disease Questionnaire" (RDQ) / "Quality of Life in Reflux and Dyspepsia" (QOLRAD) / "Gastrointestinal Quality of Life Index" (GLQI))
-Difference in the frequency of heartburn episodes per week
-Difference in the subjective perception of well-being (SF-12 questionnaire)
-Global assessment of efficacy by patient and investigator

Tolerability parameters:
-Adverse events (AEs)
-Difference in blood pressure/heart rate
-Differences in safety laboratory parameters
-Global assessment of tolerability by patient and investigator

Protection of trial subjects:

The investigators ensured that the subjects were given full and adequate oral and written information (subject information) about the nature, purpose, consequences and possible risk of the clinical study. The subjects were given the opportunity to ask questions and were allowed sufficient time to consider the information provided. Subjects provided informed consent before the conduct of any study specific procedure. The collected data were made available to the CRO and the study's sponsor only in pseudonymous form, to minimize the chances of matching the data to an individual person.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 July 2013
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	Germany: 50
Worldwide total number of subjects	50
EEA total number of subjects	50

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)	50
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment period: July 2013 - April 2014
Subjects were recruited in Berlin, Germany.

Pre-assignment

Screening details:

56 Patients were screened;
6 patients were excluded from further participation mainly due to violations of in-/exclusion criteria and non-compliance in the run-in period.

Period 1

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

Arms

Arm title	Intervention
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	St. Gero
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

1,5 l of St. Gero per day:
3 times a day 300 ml before or with a meal; the remaining volume should be consumed over the day.

Number of subjects in period 1	Intervention
Started	50
Completed	49
Not completed	1
Consent withdrawn by subject	1

Baseline characteristics

Reporting groups	
Reporting group title	Intervention

Reporting group description: -

Reporting group values	Intervention	Total	
Number of subjects	50	50	
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	40.9		
standard deviation	± 11.3	-	
Gender categorical Units: Subjects			
Female	22	22	
Male	28	28	

End points

End points reporting groups

Reporting group title	Intervention

Reporting group description: -

Primary: Difference in the frequency of heartburn episodes per week

End point title	Difference in the frequency of heartburn episodes per week[1]

End point description:

End point type	Primary

End point timeframe:

Pre / post comparison (V5-V2)

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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	48			
Units: Heartburn/week				
arithmetic mean (standard deviation)	-5.06 (± 4.81)			

Statistical analyses

No statistical analyses for this end point

Primary: Global assessment of efficacy by patient

End point title	Global assessment of efficacy by patient[2]

End point description:

End point type	Primary

End point timeframe:

post intervention

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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: Number of patients				
Very good	18			
Good	24			
Moderate	4			
Poor	1			

Statistical analyses

No statistical analyses for this end point

Primary: Global assessment of tolerability by patient

End point title	Global assessment of tolerability by patient[3]

End point description:

End point type	Primary

End point timeframe:

Post intervention

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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: Number of patients				
Very good	41			
Good	4			
Moderate	2			
Poor	0			

Statistical analyses

No statistical analyses for this end point

Primary: Global assessment of tolerability by investigator

End point title	Global assessment of tolerability by investigator[4]

End point description:

End point type	Primary

End point timeframe:

post intervention

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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: Number of cases				
Very good	42			
Good	3			
Moderate	2			
Poor	0			

Statistical analyses

No statistical analyses for this end point

Primary: Global assessment of efficacy by investigator

End point title	Global assessment of efficacy by investigator[5]

End point description:

End point type	Primary

End point timeframe:

Post intervention

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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: Number of cases				
Very good	18			
Good	25			
Moderate	3			
Poor	1			

Statistical analyses

No statistical analyses for this end point

Primary: "Reflux Disease Questionnaire" (RDQ)- heartburn

End point title	"Reflux Disease Questionnaire" (RDQ)- heartburn[6]

End point description:

End point type	Primary

End point timeframe:

Pre / post comparison (V2-V5)

Notes:

[6] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: Score				
arithmetic mean (standard deviation)				
Frequency	1.66 (± 1.86)			
Intensity	1.91 (± 2.03)			

Statistical analyses

No statistical analyses for this end point

Primary: "Reflux Disease Questionnaire" (RDQ)- regurgitation

End point title	"Reflux Disease Questionnaire" (RDQ)- regurgitation[7]

End point description:

End point type	Primary

End point timeframe:

pre / post comparison (V2-V5)

Notes:

[7] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	46			
Units: Score				
arithmetic mean (standard deviation)				
Frequency	2.48 (± 2.31)			
Intensity	2.54 (± 2.79)			

Statistical analyses

No statistical analyses for this end point

Primary: "Reflux Disease Questionnaire" (RDQ)- GERD

End point title	"Reflux Disease Questionnaire" (RDQ)- GERD[8]

End point description:

End point type	Primary

End point timeframe:

pre / post comparison (V2-V5)

Notes:

[8] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	46			
Units: Score				
arithmetic mean (standard deviation)				
Frequency	4.17 (± 3.27)			
Intensity	4.50 (± 4.09)			

Statistical analyses

No statistical analyses for this end point

Primary: "Reflux Disease Questionnaire" (RDQ)- dyspepsia

End point title	"Reflux Disease Questionnaire" (RDQ)- dyspepsia[9]

End point description:

End point type	Primary

End point timeframe:

pre / post comparison (V2-V5)

Notes:

[9] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	45			
Units: Score				
arithmetic mean (standard deviation)				
Frequency	1.73 (± 2.17)			
Intensity	1.80 (± 2.40)			

Statistical analyses

No statistical analyses for this end point

Primary: "Quality of Life in Reflux and Dyspepsia" (QOLRAD)

End point title	"Quality of Life in Reflux and Dyspepsia" (QOLRAD)[10]

End point description:

End point type	Primary

End point timeframe:

Pre / post comparison (V5-V2)

Notes:

[10] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	48			
Units: Mean score				
arithmetic mean (standard deviation)				
Emotional distress	0.84 (± 1.05)			
Sleep disturbances	0.71 (± 1.03)			
Food/drink problems	1.10 (± 1.20)			
Physical/social functioning	0.63 (± 0.84)			
Vitality	0.83 (± 1.12)			

Statistical analyses

No statistical analyses for this end point

Primary: "Gastrointestinal Quality of Life Index" (GLQI)

End point title	"Gastrointestinal Quality of Life Index" (GLQI)[11]

End point description:

End point type	Primary

End point timeframe:

pre / post comparison (V5-V2)

Notes:

[11] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	48			
Units: Score				
arithmetic mean (standard deviation)				
Total	16.6 (± 16.2)			
Symptoms	10.8 (± 9.4)			
Emotions	2.2 (± 3.1)			
Physical function	2.6 (± 4.9)			
Social function	1.0 (± 2.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Difference in the subjective perception of well-being (SF-12 questionnaire)

End point title	Difference in the subjective perception of well-being (SF-12 questionnaire)[12]

End point description:

End point type	Primary

End point timeframe:

pre / post comparison (V5-V2)

Notes:

[12] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	48			
Units: Score points				
arithmetic mean (standard deviation)				
General health	-0.44 (± 0.71)			
Moderate activities	0.06 (± 0.32)			
Climbing several flights of stairs	0.02 (± 0.33)			
Accomplished less due to physical health	0.11 (± 0.43)			
Limitations in the kind of work	0.09 (± 0.28)			

Accomplished less to to emotional problems	0.04 (± 0.46)			
Carefulness	0.02 (± 0.44)			
Pain interfering normal work	-0.46 (± 0.65)			
Felt calm and peaceful	-0.60 (± 1.27)			
A lot of energy	-0.54 (± 1.18)			
Downhearted and blue	0.44 (± 1.25)			
Social activities	0.19 (± 0.76)			

Statistical analyses

No statistical analyses for this end point

Primary: Difference in blood pressure

End point title	Difference in blood pressure[13]

End point description:

End point type	Primary

End point timeframe:

pre / post comparison (V5-V2)

Notes:

[13] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	48			
Units: mmHg				
arithmetic mean (standard deviation)				
Systolic	-3.54 (± 8.87)			
Diastolic	-3.02 (± 6.50)			

Statistical analyses

No statistical analyses for this end point

Primary: Difference in heart rate

End point title	Difference in heart rate[14]

End point description:

End point type	Primary

End point timeframe:

pre / post comparison (V5-V2)

Notes:

[14] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	48			
Units: 1/min				
arithmetic mean (standard deviation)	-2.21 (± 5.87)			

Statistical analyses

No statistical analyses for this end point

Primary: Difference in safety laboratory parameters-Hemoglobin

End point title	Difference in safety laboratory parameters-Hemoglobin[15]

End point description:

End point type	Primary

End point timeframe:

pre / post comparison (V5-V1)

Notes:

[15] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: mmol/l				
arithmetic mean (standard deviation)	0.04 (± 0.45)			

Statistical analyses

No statistical analyses for this end point

Primary: Difference in safety laboratory parameters- hematocrit

End point title	Difference in safety laboratory parameters- hematocrit[16]

End point description:

End point type	Primary

End point timeframe:

pre / post comparison (V5-V1)

Notes:

[16] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: l/l				
arithmetic mean (standard deviation)	0.001 (± 0.022)			

Statistical analyses

No statistical analyses for this end point

Primary: Difference in safety laboratory parameters - Erythrocytes

End point title	Difference in safety laboratory parameters - Erythrocytes[17]

End point description:

End point type	Primary

End point timeframe:

pre / post comparison (V5-V1)

Notes:

[17] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: Tpt/l				
arithmetic mean (standard deviation)	0.01 (± 0.23)			

Statistical analyses

No statistical analyses for this end point

Primary: Difference in safety laboratory parameters -Thrombocytes

End point title	Difference in safety laboratory parameters -Thrombocytes[18]

End point description:

End point type	Primary

End point timeframe:

pre / post comparison (V5-V1)

Notes:

[18] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: Gpt/l				
arithmetic mean (standard deviation)	-0.49 (± 24.58)			

Statistical analyses

No statistical analyses for this end point

Primary: Difference in safety laboratory parameters - Leucocytes

End point title	Difference in safety laboratory parameters - Leucocytes[19]

End point description:

End point type	Primary

End point timeframe:

pre / post comparison (V5-V1)

Notes:

[19] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: Gpt/l				
arithmetic mean (standard deviation)	-0.01 (± 1.20)			

Statistical analyses

No statistical analyses for this end point

Primary: Difference in safety laboratory parameters - ALAT

End point title	Difference in safety laboratory parameters - ALAT[20]

End point description:

End point type	Primary

End point timeframe:

pre / post comparison (V5-V1)

Notes:

[20] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: µkat/l				
arithmetic mean (standard deviation)	0.004 (± 0.125)			

Statistical analyses

No statistical analyses for this end point

Primary: Difference in safety laboratory parameters - ASAT

End point title	Difference in safety laboratory parameters - ASAT[21]

End point description:

End point type	Primary

End point timeframe:

pre / post comparison (V5-V1)

Notes:

[21] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: µkat/l				
arithmetic mean (standard deviation)	0.003 (± 0.133)			

Statistical analyses

No statistical analyses for this end point

Primary: Difference in safety laboratory parameters - gGT

End point title	Difference in safety laboratory parameters - gGT[22]

End point description:

End point type	Primary

End point timeframe:

pre /post comparison (V5-V1)

Notes:

[22] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: µkat/l				
arithmetic mean (standard deviation)	-0.032 (± 0.170)			

Statistical analyses

No statistical analyses for this end point

Primary: Difference in safety laboratory parameters - AP

End point title	Difference in safety laboratory parameters - AP[23]

End point description:

End point type	Primary

End point timeframe:

pre / post comparison (V5-V1)

Notes:

[23] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: µkat/l				
arithmetic mean (standard deviation)	-0.021 (± 0.145)			

Statistical analyses

No statistical analyses for this end point

Primary: Difference in safety laboratory parameters - Bilirubin

End point title	Difference in safety laboratory parameters - Bilirubin[24]

End point description:

End point type	Primary

End point timeframe:

pre / post comparison (V5-V1)

Notes:

[24] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: µmol/l				
arithmetic mean (standard deviation)	1.16 (± 4.65)			

Statistical analyses

No statistical analyses for this end point

Primary: Difference in safety laboratory parameters - Creatinine

End point title	Difference in safety laboratory parameters - Creatinine[25]

End point description:

End point type	Primary

End point timeframe:

pre /post comparison (V5-V1)

Notes:

[25] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: µmol/l				
arithmetic mean (standard deviation)	0.98 (± 6.85)			

Statistical analyses

No statistical analyses for this end point

Primary: Difference in safety laboratory parameters - Urea

End point title	Difference in safety laboratory parameters - Urea[26]

End point description:

End point type	Primary

End point timeframe:

(V5-V1)

Notes:

[26] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: mmol/l				
arithmetic mean (standard deviation)	0.21 (± 1.10)			

Statistical analyses

No statistical analyses for this end point

Primary: Difference in safety laboratory parameters - Uric acid

End point title	Difference in safety laboratory parameters - Uric acid[27]

End point description:

End point type	Primary

End point timeframe:

V5-V1

Notes:

[27] - 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: This was a pilot study with only one intervention arm, thus pre/post comparisons were performed in the statistical analysis.
However, it is not possible to specify this using the available entry options, as an error warning comes up stating the at least two groups need to be compared.

End point values	Intervention			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: µmol/l				
arithmetic mean (standard deviation)	3.38 (± 40.52)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: V1-V5	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.1
Reporting groups	
Reporting group title	Intervention

Reporting group description: -

Serious adverse events	Intervention		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 49 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Intervention		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 49 (4.08%)		
General disorders and administration site conditions			
Headache			
subjects affected / exposed	2 / 49 (4.08%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 November 2013	Change of investigator and project manager. Increase of maximal age for study participation from 55 years to 64 years.

Notes:

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/26909240