



Clinical trial results:

Evaluation of the effect of Gerdoff administered in combination to a treatment with protonic pump inhibitors vs the only treatment with protonic pump inhibitors, administered for 6 weeks, on higher symptoms associated to gerd, in patients with first diagnosis of gastroesophageal reflux disease. An open, multicentre, prospective, randomized, double parallel treatment arms study.

Summary

EudraCT number	2016-004503-31
Trial protocol	IT
Global end of trial date	11 December 2018

Results information

Result version number	v1 (current)
This version publication date	27 December 2019
First version publication date	27 December 2019

Trial information

Trial identification

Sponsor protocol code	PSC-DSGERDAP16
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03793556
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Sofar Spa
Sponsor organisation address	Via Firenze, 40, Trezzano Rosa, Italy, 20060
Public contact	Direzione Scientifica, SOFAR S.p.A., 0039 02 9093621, francesca.baldan@sofarfarm.it
Scientific contact	Direzione Scientifica, SOFAR S.p.A., 0039 02 9093621, walter.fiore@sofarfarm.it

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	19 July 2019
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	11 December 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the capacity of GERDOFF to improve upper symptoms related to diagnosis of GERD in association with PPI (omeprazole) vs. the only treatment with PPI (omeprazole) during 6 weeks of treatment and during the following retention period of 12 weeks.

Protection of trial subjects:

To safeguard the health and well-being of patients, and to keep under control the possible upper symptoms of GERD that could appear, all patients who continued in the follow-up period received omeprazole as rescue medication in a quantity adequate to cover the entire follow-up period. This therapy was chosen by the study coordinator as it was commonly used in clinical practice to treat all specific and non-specific symptoms of GERD. The investigator explained to patients that rescue omeprazole could be taken only if necessary and according to the indications given by the Investigator, at constant dosage, and that use was to be recorded in the daily diary by indicating the reason for administration.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 February 2017
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	Italy: 72
Worldwide total number of subjects	72
EEA total number of subjects	72

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)	62
From 65 to 84 years	9
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

A first specialist visit was performed by an ENT as per clinical practice based on patient's symptoms. Patients sent by the ENT should not have been pre-treated with PPIs and/or medical devices and/or similar products. The diagnosis was confirmed by the Gastroenterologist Investigator who recruited patients.

Pre-assignment

Screening details:

The main inclusion criteria were: male or female subjects aged ≥ 18 years; first diagnosis of GERD with upper symptoms; presence of extra-oesophageal symptoms associated with GERD; RSI score ≥ 20 ; patients not pre-treated with proton pump inhibitors in the previous 4 weeks; patients able to give the informed consent.

Pre-assignment period milestones

Number of subjects started	72
Number of subjects completed	71

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Consent withdrawn by subject: 1
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Period 1

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

Arms

Are arms mutually exclusive?	Yes
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Arm title	Omeprazole
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Arm description: -

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

Dosage and administration details:

Two 20 mg capsules once daily in the morning before breakfast.

Treatment duration: 6 weeks \pm 2 days.

Arm title	Gerdoff® + Omeprazole
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Arm description: -

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

Dosage and administration details:

Two 20 mg capsules once daily in the morning before breakfast.

Treatment duration: 6 weeks \pm 2 days.

Investigational medicinal product name	Gerdoff®
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Chewable tablet
Routes of administration	Oral use

Dosage and administration details:

One tablet three times daily: 1 tablet after breakfast, 1 tablet after lunch and 1 tablet in the evening before retiring to bed.

Treatment duration: 6 weeks \pm 2 days.

Number of subjects in period 1^[1]	Omeprazole	Gerdoff® + Omeprazole
Started	36	35
Completed	36	35

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: One patient was enrolled, but he/she did not end the pre-assignment phase

Period 2

Period 2 title	Treatment
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Omeprazole

Arm description:

Patients randomized to receive omeprazole -two 20 mg capsules once daily- for 6 weeks

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

Dosage and administration details:

Two 20 mg capsules once daily in the morning before breakfast.

Treatment duration: 6 weeks \pm 2 days.

Arm title	Gerdoff® + Omeprazole
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Arm description:

Patients randomized to receive Gerdoff® -one tablet three times daily- plus omeprazole - two 20 mg capsules once daily-

Arm type	Experimental
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Investigational medicinal product name	Gerdoff®
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Chewable tablet
Routes of administration	Oral use

Dosage and administration details:

One tablet three times daily: 1 tablet after breakfast, 1 tablet after lunch and 1 tablet in the evening before retiring to bed.

Treatment duration: 6 weeks \pm 2 days.

Investigational medicinal product name	Omeprazole
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Two 20 mg capsules once daily in the morning before breakfast.

Treatment duration: 6 weeks \pm 2 days.

Number of subjects in period 2	Omeprazole	Gerdoff® + Omeprazole
Started	36	35
Completed	34	22
Not completed	2	13
Consent withdrawn by subject	1	12
Lost to follow-up	1	1

Period 3

Period 3 title	Follow-up
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Gerdoff®

Arm description:

Responder patients of Group Gerdoff® + omeprazole were randomly assigned to receive a treatment with Gerdoff®-one tablet three times daily-

All patients received a packaging of omeprazole, to be taken only if necessary, at constant dose and according to the indications of the Investigator.

The scheduled duration of the follow-up period was 12 weeks.

Arm type	Experimental
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Investigational medicinal product name	Gerdoff®
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Chewable tablet
Routes of administration	Oral use

Dosage and administration details:

One tablet three times daily: 1 tablet after breakfast, 1 tablet after lunch and 1 tablet in the evening before retiring to bed.

Treatment duration: 6 weeks ± 2 days.

Arm title	No treated
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Arm description:

Responder patients of Group Gerdoff® + omeprazole were randomly assigned to the control group. All patients received a packaging of omeprazole, to be taken only if necessary, at constant dose and according to the indications of the Investigator.

The scheduled duration of the follow-up period was 12 weeks.

Arm type	No intervention
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No investigational medicinal product assigned in this arm

Number of subjects in period 3^[2]	Gerdoff®	No treated
Started	10	8
Completed	8	8
Not completed	2	0
Lost to follow-up	2	-

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: In the follow-up period only patients who responded to treatment were included.

Baseline characteristics

Reporting groups

Reporting group title	Omeprazole
Reporting group description: -	
Reporting group title	Gerdoff® + Omeprazole
Reporting group description: -	

Reporting group values	Omeprazole	Gerdoff® + Omeprazole	Total
Number of subjects	36	35	71
Age categorical Units: Subjects			
Adults (18-64 years)	31	30	61
From 65-84 years	5	4	9
85 years and over	0	1	1
Age continuous Units: years			
median	45.5	46.0	
full range (min-max)	20 to 76	20 to 86	-
Gender categorical Units: Subjects			
Female	32	22	54
Male	4	13	17
Patients with simultaneous symptoms Units: Subjects			
1 symptom	3	2	5
2 symptoms	1	5	6
3 symptoms	6	9	15
4 symptoms	17	11	28
5 symptoms	5	5	10
6 symptoms	3	2	5
7 symptoms	1	1	2
Not recorded	0	0	0
Hoarseness or vocal problem Units: Subjects			
yes	18	21	39
no	18	14	32
Throat clearance Units: Subjects			
yes	23	18	41
no	13	17	30
Excess of mucus in the throat or retrosternal fall of secretions Units: Subjects			
yes	15	14	29
no	21	21	42
Difficulty in swallowing food, fluids or pills Units: Subjects			

yes	7	7	14
no	29	28	57
Cough after the meal or after lying Units: Subjects			
yes	15	13	28
no	21	22	43
Difficulty in breathing or episodes of choking Units: Subjects			
yes	5	4	9
no	31	31	62
Problematic or troublesome cough Units: Subjects			
yes	24	16	40
no	12	19	31
Sensation of something blocked or mass in the throat Units: Subjects			
yes	12	17	29
no	24	18	42
Stomach burning, thoracic pain, poor digestion of gastric acid that moves upright Units: Subjects			
yes	22	17	39
no	14	18	32
Weight Units: kg median full range (min-max)	62.0 43.0 to 95.0	63.0 45.0 to 98.6	-
Body Mass Index Units: kg/m ² median full range (min-max)	22.7 16.8 to 38.6	22.6 17.6 to 35.2	-
Number of symptoms Units: number median inter-quartile range (Q1-Q3)	4 1 to 7	4 1 to 7	-

End points

End points reporting groups

Reporting group title	Omeprazole
Reporting group description: -	
Reporting group title	Gerdoff® + Omeprazole
Reporting group description: -	
Reporting group title	Omeprazole
Reporting group description:	
Patients randomized to receive omeprazole -two 20 mg capsules once daily- for 6 weeks	
Reporting group title	Gerdoff® + Omeprazole
Reporting group description:	
Patients randomized to receive Gerdoff® -one tablet three times daily- plus omeprazole - two 20 mg capsules once daily-	
Reporting group title	Gerdoff®
Reporting group description:	
Responder patients of Group Gerdoff® + omeprazole were randomly assigned to receive a treatment with Gerdoff®-one tablet three times daily-	
All patients received a packaging of omeprazole, to be taken only if necessary, at constant dose and according to the indications of the Investigator.	
The scheduled duration of the follow-up period was 12 weeks.	
Reporting group title	No treated
Reporting group description:	
Responder patients of Group Gerdoff® + omeprazole were randomly assigned to the control group.	
All patients received a packaging of omeprazole, to be taken only if necessary, at constant dose and according to the indications of the Investigator.	
The scheduled duration of the follow-up period was 12 weeks.	

Primary: Change from baseline to visit V4 of the total score of RSI questionnaire

End point title	Change from baseline to visit V4 of the total score of RSI questionnaire
End point description:	
End point type	Primary
End point timeframe:	
From baseline to visit 4 after 6 weeks of treatment	

End point values	Omeprazole	Gerdoff® + Omeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	31		
Units: number				
arithmetic mean (standard deviation)	-13.7 (± 10.58)	-16.2 (± 7.45)		

Statistical analyses

Statistical analysis title	Change of total RSI score from baseline to V4
Comparison groups	Omeprazole v Gerdoff® + Omeprazole
Number of subjects included in analysis	67
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.276
Method	Unpaired t test
Parameter estimate	Mean difference (final values)
Point estimate	-2.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.03
upper limit	2.04
Variability estimate	Standard deviation
Dispersion value	9.27

Secondary: Change of the total score of RSI questionnaire from baseline to the other time points

End point title	Change of the total score of RSI questionnaire from baseline to the other time points
End point description:	
Data from visit 2 and visit 3 are summarized in the table attached	
End point type	Secondary
End point timeframe:	
From baseline to visit V2, V3 and V4	

End point values	Omeprazole	Gerdoff® + Omeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	31		
Units: number				
arithmetic mean (standard deviation)	-13.7 (± 10.58)	-16.2 (± 7.45)		

Attachments (see zip file)	Change of the total score V2-V3/Table V2 V3.pdf
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Statistical analyses

Statistical analysis title	ANOVA
Statistical analysis description:	
The ANOVA model examined the entire curve profile.	
Comparison groups	Omeprazole v Gerdoff® + Omeprazole

Number of subjects included in analysis	67
Analysis specification	Pre-specified
Analysis type	other ^[1]
P-value	= 0.0157
Method	ANOVA

Notes:

[1] - The ANOVA model showed a statistically significant treatment effect (F value = 6.13, p = 0.0157) and a statistically significant visit effect (F value = 73.00, p<0.0001), whereas the treatment-by-visit interaction was not statistically significant (F value = 1.07, p = 0.3695).

Secondary: Change from baseline to visit 4 of the RSI questionnaire score of hoarseness or vocal problem

End point title	Change from baseline to visit 4 of the RSI questionnaire score of hoarseness or vocal problem
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End point description:

End point type	Secondary
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End point timeframe:

Visit 4 after 6 weeks of treatment

End point values	Omeprazole	Gerdoff® + Omeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	31		
Units: number				
arithmetic mean (standard deviation)	1.6 (± 1.54)	1.1 (± 1.33)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to visit 4 of the RSI questionnaire score of throat clearance

End point title	Change from baseline to visit 4 of the RSI questionnaire score of throat clearance
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End point description:

End point type	Secondary
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End point timeframe:

At visit 4 after 6 weeks of treatment

End point values	Omeprazole	Gerdoff® + Omeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	31		
Units: number				
arithmetic mean (standard deviation)	1.8 (± 1.37)	1.4 (± 1.39)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to visit 4 of the RSI questionnaire score of excess of mucus in the throat or retrosternal fall of secretions

End point title	Change from baseline to visit 4 of the RSI questionnaire score of excess of mucus in the throat or retrosternal fall of secretions
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End point description:

End point type	Secondary
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End point timeframe:

At visit 4 after 6 weeks of treatment

End point values	Omeprazole	Gerdoff® + Omeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	31		
Units: number				
arithmetic mean (standard deviation)	1.9 (± 1.61)	1.4 (± 1.31)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to visit 4 of the RSI questionnaire score of difficulty in swallowing food, fluids or pills

End point title	Change from baseline to visit 4 of the RSI questionnaire score of difficulty in swallowing food, fluids or pills
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End point description:

End point type	Secondary
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End point timeframe:

At visit 4 after 6 weeks of treatment

End point values	Omeprazole	Gerdoff® + Omeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	31		
Units: number				
arithmetic mean (standard deviation)	0.6 (± 0.94)	0.4 (± 0.71)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to visit 4 of the RSI questionnaire score of cough after the meal or after lying

End point title	Change from baseline to visit 4 of the RSI questionnaire score of cough after the meal or after lying
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End point description:

End point type	Secondary
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End point timeframe:

At visit 4 after weeks of treatment

End point values	Omeprazole	Gerdoff® + Omeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	31		
Units: number				
arithmetic mean (standard deviation)	1.7 (± 1.47)	0.7 (± 1.01)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to visit 4 of the RSI questionnaire score of difficulty in breathing or episodes of choking

End point title	Change from baseline to visit 4 of the RSI questionnaire score of difficulty in breathing or episodes of choking
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End point description:

End point type	Secondary
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End point timeframe:

At visit 4 after 6 weeks of treatment

End point values	Omeprazole	Gerdoff® + Omeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	31		
Units: number				
arithmetic mean (standard deviation)	0.6 (± 0.97)	0.5 (± 1.15)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to visit 4 of the RSI questionnaire score of problematic or troublesome cough

End point title	Change from baseline to visit 4 of the RSI questionnaire score of problematic or troublesome cough
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End point description:

End point type	Secondary
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End point timeframe:

At visit 4 after 6 weeks of treatment

End point values	Omeprazole	Gerdoff® + Omeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	31		
Units: number				
arithmetic mean (standard deviation)	1.5 (± 1.54)	0.8 (± 1.17)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to visit 4 of the RSI questionnaire score of sensation of something blocked or mass in the throat

End point title	Change from baseline to visit 4 of the RSI questionnaire score of sensation of something blocked or mass in the throat
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End point description:

End point type	Secondary
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End point timeframe:

At visit 4 after 6 weeks of treatment

End point values	Omeprazole	Gerdoff® + Omeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	31		
Units: number				
arithmetic mean (standard deviation)	1.2 (± 1.45)	0.8 (± 1.34)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to visit 4 of the RSI questionnaire score of stomach burning, thoracic pain, poor digestion of gastric acid that moves upright

End point title	Change from baseline to visit 4 of the RSI questionnaire score of stomach burning, thoracic pain, poor digestion of gastric acid that moves upright
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End point description:

End point type	Secondary
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End point timeframe:

At visit 4 after 6 weeks of treatment

End point values	Omeprazole	Gerdoff® + Omeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	31		
Units: number				
arithmetic mean (standard deviation)	1.6 (± 1.59)	0.8 (± 1.08)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number and percentage of responders V4

End point title	Number and percentage of responders V4
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End point description:

A responder was defined as a patient who at the 6th week of treatment showed a reduction of at least 50% vs. the baseline and an absolute value < 13.

End point type	Secondary
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End point timeframe:

At visit 4 after 6 weeks of treatment

End point values	Omeprazole	Gerdoff® + Omeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	31		
Units: Subject				
YES	20	23		
NO	16	8		

Attachments (see zip file)	Percentage of responders v4/Percentage of responders V4.pdf
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Statistical analyses

Statistical analysis title	Number of responders
Comparison groups	Omeprazole v Gerdoff® + Omeprazole
Number of subjects included in analysis	67
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0496
Method	Chi-squared

Secondary: Number and percentage of responders V6

End point title	Number and percentage of responders V6
End point description:	The rate of responders was 100% in Gerdoff® group and 87.5% in control group
End point type	Secondary
End point timeframe:	In the Visit 6 at the end of follow-up

End point values	Gerdoff®	No treated		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	8		
Units: subject				
Missing	0	0		
Yes	9	7		
No	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Change of upper symptoms using the Likert scale from baseline to V4

and V6

End point title	Change of upper symptoms using the Likert scale from baseline to V4 and V6
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End point description:

Data related to visit 4 are reported here, while data related to visit 6 are presented in the table attached

End point type	Secondary
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End point timeframe:

From baseline to visit 4 after 6 weeks of treatment and to visit 6 after 18 weeks of treatment

End point values	Omeprazole	Gerdoff® + Omeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	31		
Units: Score				
arithmetic mean (standard deviation)	11.6 (± 8.083)	7.4 (± 5.667)		

Attachments (see zip file)	Likert V6/Likert scale V6.pdf
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Statistical analyses

Statistical analysis title	Upper symptoms Likert Scale V4
Comparison groups	Omeprazole v Gerdoff® + Omeprazole
Number of subjects included in analysis	67
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0065 ^[2]
Method	ANOVA

Notes:

[2] - ANOVA model showed a significant treatment effects (F value = 7.86, p = 0.0065) and a statistically significant visit effect (F value = 42.32, p<0.0001), whereas the treatment-by-visit interaction was not significant (F value = 0.59, p = 0.6240)

Secondary: Presence of upper symptoms at baseline, end of treatment, and end of follow-up using the RSI questionnaire and the Likert scale

End point title	Presence of upper symptoms at baseline, end of treatment, and end of follow-up using the RSI questionnaire and the Likert scale
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End point description:

Data related to visit 4 are reported here, while data related to visit 6 are presented in the table attached

End point type	Secondary
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End point timeframe:

The presence of upper simultaneous symptoms was assessed at baseline, at the visit 4 after 6 weeks of treatment and at the visit 6 after 18 weeks of treatment.

End point values	Omeprazole	Gerdoff® + Omeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	31		
Units: subject				
Missing	4	1		
1 symptom	2	7		
2 symptoms	9	6		
3 symptoms	11	13		
4 symptoms	7	4		
5 symptoms	2	0		
6 symptoms	1	0		

Attachments (see zip file)	Upper symptoms Likert V6/Upper Symptoms Likert V6.pdf
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Statistical analyses

No statistical analyses for this end point

Secondary: Use of rescue medication (omeprazole) during the treatment

End point title	Use of rescue medication (omeprazole) during the treatment
End point description:	Percentage of patients who used omeprazole as rescue medication are reported in the table attached.
End point type	Secondary
End point timeframe:	During the treatment from baseline to visit 4

End point values	Omeprazole	Gerdoff® + Omeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	31		
Units: subject				
Missing	0	0		
Yes	28	24		
No	8	11		

Attachments (see zip file)	Rescue Medication/Treatment.docx
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Statistical analyses

No statistical analyses for this end point

Secondary: Use of rescue medication (omeprazole) during the follow-up

End point title	Use of rescue medication (omeprazole) during the follow-up
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End point description:

End point type	Secondary
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End point timeframe:

At visit 6

End point values	Gerdoff®	No treated		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	8		
Units: subject				
missing	0	0		
Yes	7	5		
No	2	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Use of rescue medication (other than omeprazole) during treatment and follow-up

End point title	Use of rescue medication (other than omeprazole) during treatment and follow-up
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End point description:

Data related to visit 4 are reported here, data related to visit 6 are reported in the table attached.

End point type	Secondary
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End point timeframe:

From baseline to visit 4 and up to visit 6 at the end of follow-up

End point values	Omeprazole	Gerdoff® + Omeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	31		
Units: subject				
Missing	0	0		
Yes	4	0		
No	32	31		

Statistical analyses

No statistical analyses for this end point

Secondary: Patients'satisfaction

End point title	Patients'satisfaction
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End point description:

data related to visit 4 are reported here, data related to other time points and percentages are presented in the table attached.

End point type	Secondary
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End point timeframe:

During the treatment at visit 2, visit 3 and visit 4 and at the end of follow-up (visit 6).

End point values	Omeprazole	Gerdoff® + Omeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	35		
Units: subject				
Missing	0	3		
Low	1	3		
Discrete	7	1		
Good	11	11		
Excellent	17	15		

Attachments (see zip file)	Satisfaction/Satisfaction.pdf
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Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the enrollment to the end of study

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.1
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Reporting groups

Reporting group title	Omeprazole
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Reporting group description: -

Reporting group title	Gerdoff® + Omeprazole
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Reporting group description: -

Serious adverse events	Omeprazole	Gerdoff® + Omeprazole	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 36 (2.78%)	0 / 35 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
Atrial Fibrillation	Additional description: Mild intensity atrial fibrillation, not related to treatment		
subjects affected / exposed	1 / 36 (2.78%)	0 / 35 (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: 2 %

Non-serious adverse events	Omeprazole	Gerdoff® + Omeprazole	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 36 (33.33%)	14 / 35 (40.00%)	
Investigations			
Red blood cell sedimentation rate increased			
subjects affected / exposed	0 / 36 (0.00%)	1 / 35 (2.86%)	
occurrences (all)	0	1	
C-reactive protein increased			

subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	1 / 35 (2.86%) 1	
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 1	0 / 35 (0.00%) 0	
Nervous system disorders Clonus subjects affected / exposed occurrences (all) Migraine subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0 0 / 36 (0.00%) 0 0 / 36 (0.00%) 0	1 / 35 (2.86%) 1 2 / 35 (5.71%) 3 1 / 35 (2.86%) 1	
General disorders and administration site conditions Flu-like symptoms subjects affected / exposed occurrences (all) Chills subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all)	2 / 36 (5.56%) 2 0 / 36 (0.00%) 0 2 / 36 (5.56%) 2	3 / 35 (8.57%) 5 1 / 35 (2.86%) 1 0 / 35 (0.00%) 0	
Immune system disorders Hypersensitivity subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	1 / 35 (2.86%) 1	
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all) Diarrhoea	3 / 36 (8.33%) 3	4 / 35 (11.43%) 4	

subjects affected / exposed occurrences (all)	2 / 36 (5.56%) 2	0 / 35 (0.00%) 0	
Dyspepsia subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	1 / 35 (2.86%) 1	
Dysentery subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 1	1 / 35 (2.86%) 1	
Abdominal pain upper subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 1	0 / 35 (0.00%) 0	
Constipation subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 1	0 / 35 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders Bronchospasm subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	1 / 35 (2.86%) 1	
Hepatobiliary disorders Hypertransaminasaemia subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 1	0 / 35 (0.00%) 0	
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 2	0 / 35 (0.00%) 0	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 3	0 / 35 (0.00%) 0	
neck pain subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 2	1 / 35 (2.86%) 1	
Infections and infestations Gastroenteritis			

subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 1	0 / 35 (0.00%) 0	
Infection subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 1	0 / 35 (0.00%) 0	
Nasopharyngitis subjects affected / exposed occurrences (all)	2 / 36 (5.56%) 2	1 / 35 (2.86%) 1	
Sinusitis subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	1 / 35 (2.86%) 1	
Metabolism and nutrition disorders Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 1	0 / 35 (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