



Clinical trial results:

Comparison of the efficacy and safety of the fixed-dose combination of xylometazoline and dexamethasone in SeptaNasal® and xylometazoline in nasal congestion in patients after surgery in the nose and paranasal cavity and in patients with acute rhinitis – SeptaNasal DOUBLE clinical study.

Summary

EudraCT number	2015-005155-27
Trial protocol	SI HR
Global end of trial date	06 March 2018

Results information

Result version number	v1 (current)
This version publication date	04 June 2020
First version publication date	04 June 2020
Summary attachment (see zip file)	Final Report Synopsis (EN_Septanazal_DOUBLE_Final_Report-SYNOPSIS.pdf)

Trial information

Trial identification

Sponsor protocol code	KCT09/2015-SeptaNasal-Double
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Krka d.d., Novo mesto
Sponsor organisation address	Dunajska cesta 65, Ljubljana, Slovenia, 1000
Public contact	Tanja Kohek, Krka d.d., Novo mesto Dunajska cesta 65 1000 Ljubljana Slovenia, 00386 41589769, tanja.kohek@krka.biz
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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	31 July 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 March 2018
Global end of trial reached?	Yes
Global end of trial date	06 March 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of the double blind, randomized trial is to compare the efficacy of the treatment between fixed combination of xylometazoline and dexpanthenol (Septanazol®), nasal spray, and xylometazoline, nasal spray, on nasal congestion and the healing effect of dexpanthenol in patients with acute rhinitis and in patients after surgery in the nose and paranasal cavity.

Protection of trial subjects:

Patients were not included in the clinical study if they were hypersensitive to the active substances or to any of the excipients, if they had dry nasal inflammation, if they received local or systemic flu treatment, sympathomimetics or if they concomitantly received another nasal decongestant.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 January 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	Slovenia: 17
Country: Number of subjects enrolled	Croatia: 177
Worldwide total number of subjects	194
EEA total number of subjects	194

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)	194
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

There were 154 patients with acute rhinitis (Group 1) and 40 patients after an operation in the nose and paranasal cavities (Group 2) enrolled in the study.

Pre-assignment

Screening details:

In general, patients aged 18-60 years, with nasal occlusion after an operation in the nose and paranasal cavities or with acute rhinitis, were eligible for inclusion in the study. Eligible patients needed to tolerate intranasal administration of the IMP and sign informed consent form (ICF).

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Acute Rhinitis + Xylometazoline

Arm description:

Patients with acute Rhinitis who were treated only with Xylometazoline. There were 154 patients altogether with acute Rhinitis. 80 were treated only with Xylometazoline and 74 were treated with Xylometazoline and Dexpanthenol.

Arm type	Experimental
Investigational medicinal product name	Nasal spray with Xylometazoline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Nasal use

Dosage and administration details:

Nasal spray with 0.1% Xylometazoline 3 times per day 1 spray in each nostril.

Arm title	Acute Rhinitis + Xylometazoline + Dexpanthenol
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Arm description:

Patients with acute Rhinitis who were treated with Xylometazoline and Dexpanthenol. There were 154 patients altogether with acute Rhinitis. 80 were treated only with Xylometazoline and 74 were treated with Xylometazoline and Dexpanthenol.

Arm type	Experimental
Investigational medicinal product name	Nasal spray with Xylometazoline and Dexpanthenol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Nasal use

Dosage and administration details:

Nasal spray with 0.1% Xylometazoline and 5% Dexpanthenol 3 times per day 1 spray in each nostril.

Arm title	Nose operation + Xylometazoline
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Arm description:

Patients after an operation in the nose and paranasal cavities who were treated only with Xylometazoline. There were 40 patients altogether after an operation in the nose and paranasal cavities. 23 were treated only with Xylometazoline and 17 were treated with Xylometazoline and Dexpanthenol.

Arm type	Experimental
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Investigational medicinal product name	Nasal spray with Xylometazoline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Nasal use
Dosage and administration details:	
Nasal spray with 0.1% Xylometazoline 3 times per day 1 spray in each nostril.	
Arm title	Nose operation + Xylometazoline + Dexpanthenol

Arm description:

Patients after an operation in the nose and paranasal cavities who were treated with Xylometazoline and Dexpanthenol. There were 40 patients altogether after an operation in the nose and paranasal cavities. 23 were treated only with Xylometazoline and 17 were treated with Xylometazoline and Dexpanthenol.

Arm type	Experimental
Investigational medicinal product name	Nasal spray with Xylometazoline and Dexpanthenol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray, solution
Routes of administration	Nasal use

Dosage and administration details:

Nasal spray with 0.1% Xylometazoline and 5% Dexpanthenol 3 times per day 1 spray in each nostril.

Number of subjects in period 1	Acute Rhinitis + Xylometazoline	Acute Rhinitis + Xylometazoline + Dexpanthenol	Nose operation + Xylometazoline
Started	80	74	23
Completed	79	72	23
Not completed	1	2	0
Lost to follow-up	1	2	-

Number of subjects in period 1	Nose operation + Xylometazoline + Dexpanthenol
Started	17
Completed	17
Not completed	0
Lost to follow-up	-

Baseline characteristics

Reporting groups

Reporting group title	Acute Rhinitis + Xylometazoline
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Reporting group description:

Patients with acute Rhinitis who were treated only with Xylometazoline. There were 154 patients altogether with acute Rhinitis. 80 were treated only with Xylometazoline and 74 were treated with Xylometazoline and Dexpanthenol.

Reporting group title	Acute Rhinitis + Xylometazoline + Dexpanthenol
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Reporting group description:

Patients with acute Rhinitis who were treated with Xylometazoline and Dexpanthenol. There were 154 patients altogether with acute Rhinitis. 80 were treated only with Xylometazoline and 74 were treated with Xylometazoline and Dexpanthenol.

Reporting group title	Nose operation + Xylometazoline
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Reporting group description:

Patients after an operation in the nose and paranasal cavities who were treated only with Xylometazoline. There were 40 patients altogether after an operation in the nose and paranasal cavities. 23 were treated only with Xylometazoline and 17 were treated with Xylometazoline and Dexpanthenol.

Reporting group title	Nose operation + Xylometazoline + Dexpanthenol
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Reporting group description:

Patients after an operation in the nose and paranasal cavities who were treated with Xylometazoline and Dexpanthenol. There were 40 patients altogether after an operation in the nose and paranasal cavities. 23 were treated only with Xylometazoline and 17 were treated with Xylometazoline and Dexpanthenol.

Reporting group values	Acute Rhinitis + Xylometazoline	Acute Rhinitis + Xylometazoline + Dexpanthenol	Nose operation + Xylometazoline
Number of subjects	80	74	23
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
The age data is available for all patients with acute Rhinitis and for all patients after surgery in nose and paranasal cavities regardless of the IMP. Arithmetic mean of age of patients with acute Rhinitis (154) was 39.2 years (SD 11.78) and of patients after operation in nose and paranasal cavities (40) was 41.6 years (SD 11.03).			
Units: years			
arithmetic mean	39.2	39.2	41.6
standard deviation	± 11.78	± 11.78	± 11.03
Gender categorical			
For 2 patients in Arm 1 (Acute Rhinitis + Xylomethazoline), for 1 patient in Arm 3 (Nose operation + Xylomethazoline) and for 1 patient in Arm 4 (Nose operation + Xylomethazoline + Dexpanthenol) we do not have the data on the gender.			
Units: Subjects			

Female	49	51	7
Male	29	23	15
NA	2	0	1

Reporting group values	Nose operation + Xylometazoline + Dexpanthenol	Total	
Number of subjects	17	194	
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			
The age data is available for all patients with acute Rhinitis and for all patients after surgery in nose and paranasal cavities regardless of the IMP. Arithmetic mean of age of patients with acute Rhinitis (154) was 39.2 years (SD 11.78) and of patients after operation in nose and paranasal cavities (40) was 41.6 years (SD 11.03).			
Units: years			
arithmetic mean	41.6		
standard deviation	± 11.03	-	
Gender categorical			
For 2 patients in Arm 1 (Acute Rhinitis + Xylomethazoline), for 1 patient in Arm 3 (Nose operation + Xylomethazoline) and for 1 patient in Arm 4 (Nose operation + Xylomethazoline + Dexpanthenol) we do not have the data on the gender.			
Units: Subjects			
Female	3	110	
Male	13	80	
NA	1	4	

End points

End points reporting groups

Reporting group title	Acute Rhinitis + Xylometazoline
Reporting group description: Patients with acute Rhinitis who were treated only with Xylometazoline. There were 154 patients altogether with acute Rhinitis. 80 were treated only with Xylometazoline and 74 were treated with Xylometazoline and Dexpanthenol.	
Reporting group title	Acute Rhinitis + Xylometazoline + Dexpanthenol
Reporting group description: Patients with acute Rhinitis who were treated with Xylometazoline and Dexpanthenol. There were 154 patients altogether with acute Rhinitis. 80 were treated only with Xylometazoline and 74 were treated with Xylometazoline and Dexpanthenol.	
Reporting group title	Nose operation + Xylometazoline
Reporting group description: Patients after an operation in the nose and paranasal cavities who were treated only with Xylometazoline. There were 40 patients altogether after an operation in the nose and paranasal cavities. 23 were treated only with Xylometazoline and 17 were treated with Xylometazoline and Dexpanthenol.	
Reporting group title	Nose operation + Xylometazoline + Dexpanthenol
Reporting group description: Patients after an operation in the nose and paranasal cavities who were treated with Xylometazoline and Dexpanthenol. There were 40 patients altogether after an operation in the nose and paranasal cavities. 23 were treated only with Xylometazoline and 17 were treated with Xylometazoline and Dexpanthenol.	

Primary: Investigator`s assessment of nasal patency using anterior Rhinoscopy

End point title	Investigator`s assessment of nasal patency using anterior Rhinoscopy
End point description: The primary objective was to compare the efficacy of nasal sprays of a fixed combination of xylometazoline and dexpanthenol (Septanazal®) and xylometazoline in the nasal congestion of patients with acute rhinitis and patients after operation in the nose and paranasal cavities. The researcher examined the right and left nasal cavities of all patients using anterior rhinoscopy and evaluated the degree of global patency in the nasal cavity determined by the VAS (Visual Analogue Scale) scale (0 - complete nasal patency, 10 - completely occluded nose). The examination was performed on Visit 1 (Day 1), Visit 2 (Day 3) and Visit 3 (Day 7). In all patients (treated with either Septanazal or xylometazoline), the patency in both nasal cavities improved during treatment, which is directly indicated by a decrease in nasal obstruction from the first to the last visit.	
End point type	Primary
End point timeframe: 7 days for one patient and was the same for the whole duration of the study.	

End point values	Acute Rhinitis + Xylometazoline	Acute Rhinitis + Xylometazoline + Dexpanthenol	Nose operation + Xylometazoline	Nose operation + Xylometazoline + Dexpanthenol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	80	74	23	17
Units: mm on VAS				
arithmetic mean (standard deviation)				
Right nasal cavity Visit 1	7.0 (± 1.4)	7.2 (± 1.6)	5.5 (± 2.3)	4.7 (± 2.2)

Left nasal cavity Visit 1	7.0 (± 1.4)	6.9 (± 1.6)	5.6 (± 2.3)	3.9 (± 2.6)
Right nasal cavity Visit 2	4.6 (± 1.4)	4.9 (± 1.5)	4.8 (± 2.5)	3.4 (± 1.5)
Left nasal cavity Visit 2	4.7 (± 1.5)	4.8 (± 1.4)	4.9 (± 2.6)	2.6 (± 1.5)
Right nasal cavity Visit 3	2.2 (± 1.4)	2.3 (± 1.5)	3.2 (± 2.8)	2.0 (± 1.5)
Left nasal cavity Visit 3	2.1 (± 1.4)	2.1 (± 1.5)	3.5 (± 3.0)	2.0 (± 1.7)

Statistical analyses

Statistical analysis title	Nasal patency across visits
Statistical analysis description: The efficacy of Septanazal and xylometazoline in the reduction of nasal occlusion was compared between visits using asymptotic z-test. Both Septanazal and xylometazoline expressed statistically significant reduction in nasal occlusion between visits 1 and 2, 2 and 3 as well as 1 and 3.	
Comparison groups	Acute Rhinitis + Xylometazoline v Acute Rhinitis + Xylometazoline + Dexpanthenol v Nose operation + Xylometazoline v Nose operation + Xylometazoline + Dexpanthenol
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	asymptotic z-test

Primary: Patient`s assessment of nasal patency

End point title	Patient`s assessment of nasal patency
End point description: The primary objective was to compare the efficacy of nasal sprays of a fixed combination of xylometazoline and dexpanthenol (Septanazal®) and xylometazoline in the nasal congestion of patients with acute rhinitis and patients after operation in the nose and paranasal cavities. The patient also evaluated nasal patency using a VAS scale. Nasal patency was assessed before IMP administration and 1 minute, 3 minutes, 6 minutes and 9 minutes after IMP administration. Both Septanazal and xylometazoline effect was observed within 1 minute of administration. Even greater is the reduction of nasal occlusion after 3, 6 and 9 minutes after application of any IMP. There were no statistically significant differences between Septanazal and xylometazoline before and 1 minute, 3 minutes, 6 minutes and 9 minutes after IMP administration.	
End point type	Primary
End point timeframe: 7 days for one patient and was the same for the whole duration of the study.	

End point values	Acute Rhinitis + Xylometazoline	Acute Rhinitis + Xylometazoline + Dexpanthenol	Nose operation + Xylometazoline	Nose operation + Xylometazoline + Dexpanthenol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	80	74	23	17
Units: mm on VAS				
arithmetic mean (standard deviation)				
Before IMP	7.11 (± 1.75)	7.40 (± 1.55)	4.85 (± 2.59)	4.55 (± 2.22)

1 minute after IMP	5.13 (± 1.82)	5.32 (± 2.07)	3.64 (± 2.04)	3.74 (± 2.35)
3 minutes after IMP	3.84 (± 1.74)	4.15 (± 1.91)	3.42 (± 2.61)	2.94 (± 2.25)
6 minutes after IMP	3.00 (± 1.79)	3.43 (± 1.90)	3.00 (± 2.40)	2.36 (± 1.99)
9 minutes after IMP	2.48 (± 1.81)	2.89 (± 1.97)	2.82 (± 2.45)	1.99 (± 2.00)

Statistical analyses

Statistical analysis title	Comparing efficacy of nasal sprays
Statistical analysis description:	
The efficacy of Septanazal and xylomethazoline in the reduction of nasal occlusion was compared with the statistical comparison of means of VAS reductions in patients treated with Septanazal and patients treated with xylomethazoline, using either the unpaired t-test or the Wilcoxon-Mann-Whitney test, if the assumptions for unpaired t-test were not met.	
Comparison groups	Acute Rhinitis + Xylometazoline v Acute Rhinitis + Xylometazoline + Dexpanthenol v Nose operation + Xylometazoline v Nose operation + Xylometazoline + Dexpanthenol
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	other ^[1]
P-value	< 0.05
Method	t-test, 2-sided

Notes:

[1] - In patients with acute Rhinitis (Group 1) all differences between Septanazal and xylomethazoline efficacy were statistically insignificant (before IMP P=0.28185, 1 min P=0.55145, 3 min P=0.29645, 6 min P=0.15029, 9 min P=0.17259).

In patients with after nose surgery (Group 2) all differences between Septanazal and xylomethazoline efficacy were statistically insignificant (before IMP P=0.70127, 1 min P=0.88677, 3 min P=0.50163, 6 min P=0.36600, 9 min P=0.24734).

Primary: Questionnaire SNOT-22 REV 2 - "Nose occlusion"

End point title	Questionnaire SNOT-22 REV 2 - "Nose occlusion"
End point description:	
SNOT-22 REV 2 is a questionnaire used to evaluate acute inflammation of the nasal mucosa and chronic inflammation of the nasal mucosa and the paranasal cavities. Of the 22 questions asked, one was about "nose occlusion". The question was evaluated with points from 0 to 5, with the number representing the severity of the symptoms (0 - symptom no problem, 5 - symptom most severe).	
PATIENTS AFTER NOSE SURGERY: A statistically significant comparison of the average values of nasal occlusion was found at the 3rd visit, in favor of Septanazal and was 1.0, p=0.020. Comparison of differences in reduction of nasal occlusion from V1 to V3 between the two studied groups was statistically insignificant.	
PATIENTS WITH ACUTE RHINITIS: Average values of nasal occlusion on 1st and 3rd visit as well as comparison of differences in reduction of nasal occlusion from V1 to V3 between the two studied groups were statistically insignificant.	
End point type	Primary
End point timeframe:	
7 days for one patient and was the same for the whole duration of the study.	

End point values	Acute Rhinitis + Xylometazoline	Acute Rhinitis + Xylometazoline + Dexpanthenol	Nose operation + Xylometazoline	Nose operation + Xylometazoline + Dexpanthenol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	80	74	23	17
Units: points				
arithmetic mean (standard deviation)				
Visit 1 (Day 1)	3.6 (± 0.91)	3.9 (± 0.87)	3.6 (± 1.24)	3.2 (± 1.13)
Visit 3 (Day 7)	1.3 (± 0.93)	1.4 (± 1.17)	1.9 (± 1.35)	0.9 (± 1.12)

Statistical analyses

Statistical analysis title	SNOT-22 REV 2 - Nose occlusion
Comparison groups	Acute Rhinitis + Xylometazoline v Acute Rhinitis + Xylometazoline + Dexpanthenol v Nose operation + Xylometazoline v Nose operation + Xylometazoline + Dexpanthenol
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided

Primary: Patient`s subjective assessment of obstructed breathing

End point title	Patient`s subjective assessment of obstructed breathing
End point description:	<p>After the IMP application, the patient evaluated the severity of 11 symptoms on a scale from 0 to 4 (0 - symptom no problems, 4 - symptom very serious problems). One of the symptoms was the "sensation of obstructed breathing through the nose", which directly indicates nasal occlusion. The evaluation took place at all three visits.</p> <p>PATIENTS AFTER NOSE SURGERY: The observed symptom decreased statistically significantly from the V1 to the V3 (decrease by 41% in the xylometazoline group (p = 0.031) and 49% in the Septanazal group (p = 0.004)).</p> <p>PATIENTS WITH ACUTE RHINITIS: The observed symptom decreased statistically significantly from the V1 to the V3 (a decrease of 63% in the xylometazoline group (p <0.0001) and 64% in the Septanazal group (p <0.0001)).</p>
End point type	Primary
End point timeframe:	7 days for one patient and was the same for the whole duration of the study.

End point values	Acute Rhinitis + Xylometazoline	Acute Rhinitis + Xylometazoline + Dexpanthenol	Nose operation + Xylometazoline	Nose operation + Xylometazoline + Dexpanthenol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	80	74	23	17

Units: points				
arithmetic mean (standard deviation)				
Visit 1 (Day 1)	2.2 (\pm 1.09)	2.4 (\pm 1.10)	2.0 (\pm 1.51)	1.4 (\pm 1.32)
Visit 2 (Day 3)	1.5 (\pm 0.9)	1.8 (\pm 0.87)	1.6 (\pm 1.16)	1.1 (\pm 0.68)
Visit 3 (Day 7)	0.8 (\pm 0.62)	0.9 (\pm 0.71)	1.2 (\pm 0.98)	0.7 (\pm 0.79)

Statistical analyses

Statistical analysis title	Patient`s subjective assessment
Comparison groups	Acute Rhinitis + Xylometazoline v Acute Rhinitis + Xylometazoline + Dexpanthenol v Nose operation + Xylometazoline v Nose operation + Xylometazoline + Dexpanthenol
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided

Primary: Global assessment of individual`s behavior - GAIB

End point title	Global assessment of individual`s behavior - GAIB
End point description:	
At V2 and V3, the investigator evaluated the improvement in signs and symptoms during treatment using GAIB. GAIB contains a 7-point rating (0 - fully improved, 6 - worse disease/condition than at baseline). GAIB compared the end state versus the severity of the initial condition. PATIENTS AFTER NOSE SURGERY: The mean score decreased from V2 to V3 for 0.38 (35%, P=0.0078) in the group treated with Septanazal and for 0.39 (25%, P=0.0019) in the group treated with xylometazoline. Comparison of mean global estimates of improvement did not show a statistically significant difference between the groups studied. PATIENTS WITH ACUTE RHINITIS: The mean score decreased from V2 to V3 for 0.96 (52%, P<0.0001) in the group treated with Septanazal and for 0.72 (47%, P<0.0001) in the group treated with xylometazoline. Comparison of mean global estimates of improvement showed a statistically significant difference between the groups only on V2 with Septanazal group having a higher score (p<0.027).	
End point type	Primary
End point timeframe:	
7 days for one patient and was the same for the whole duration of the study.	

End point values	Acute Rhinitis + Xylometazoline	Acute Rhinitis + Xylometazoline + Dexpanthenol	Nose operation + Xylometazoline	Nose operation + Xylometazoline + Dexpanthenol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	80	73	23	16
Units: points				
arithmetic mean (standard deviation)				
Visit 2 (Day 3)	1.53 (\pm 0.90)	1.84 (\pm 0.87)	1.57 (\pm 1.16)	1.06 (\pm 0.68)
Visit 3 (Day 7)	0.81 (\pm 0.62)	0.88 (\pm 0.71)	1.17 (\pm 0.98)	0.69 (\pm 0.79)

Statistical analyses

Statistical analysis title	Global assessment of individual`s behavior
Comparison groups	Acute Rhinitis + Xylometazoline v Acute Rhinitis + Xylometazoline + Dexpanthenol v Nose operation + Xylometazoline v Nose operation + Xylometazoline + Dexpanthenol
Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Timeframe for AE reporting for one patient was 7 days and was the same for the whole duration of the study (from the day the first patient entered (23.1.2017) to the day the last patient concluded the study (6.3.2018)).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	Acute Rhinitis + Xylometazoline
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Reporting group description:

Patients with acute Rhinitis who were treated only with Xylometazoline. There were 154 patients altogether with acute Rhinitis. 80 were treated only with Xylometazoline and 74 were treated with Xylometazoline and Dexpanthenol.

Reporting group title	Acute Rhinitis + Xylometazoline + Dexpanthenol
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Reporting group description:

Patients with acute Rhinitis who were treated with Xylometazoline and Dexpanthenol. There were 154 patients altogether with acute Rhinitis. 80 were treated only with Xylometazoline and 74 were treated with Xylometazoline and Dexpanthenol.

Reporting group title	Nose operation + Xylometazoline
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Reporting group description:

Patients after an operation in the nose and paranasal cavities who were treated only with Xylometazoline. There were 40 patients altogether after an operation in the nose and paranasal cavities. 24 were treated only with Xylometazoline and 16 were treated with Xylometazoline and Dexpanthenol.

Reporting group title	Nose operation + Xylometazoline + Dexpanthenol
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Reporting group description:

Patients after an operation in the nose and paranasal cavities who were treated with Xylometazoline and Dexpanthenol. There were 40 patients altogether after an operation in the nose and paranasal cavities. 24 were treated only with Xylometazoline and 16 were treated with Xylometazoline and Dexpanthenol.

Serious adverse events	Acute Rhinitis + Xylometazoline	Acute Rhinitis + Xylometazoline + Dexpanthenol	Nose operation + Xylometazoline
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 80 (0.00%)	0 / 74 (0.00%)	0 / 23 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	Nose operation + Xylometazoline + Dexpanthenol		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 17 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Acute Rhinitis + Xylometazoline	Acute Rhinitis + Xylometazoline + Dexpanthenol	Nose operation + Xylometazoline
Total subjects affected by non-serious adverse events subjects affected / exposed	4 / 80 (5.00%)	7 / 74 (9.46%)	2 / 23 (8.70%)
Vascular disorders			
Bleeding nose			
subjects affected / exposed	2 / 80 (2.50%)	5 / 74 (6.76%)	0 / 23 (0.00%)
occurrences (all)	2	5	0
Hypertension			
subjects affected / exposed	0 / 80 (0.00%)	0 / 74 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Head pressure			
subjects affected / exposed	0 / 80 (0.00%)	0 / 74 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 80 (0.00%)	2 / 74 (2.70%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Nasal burning			
subjects affected / exposed	1 / 80 (1.25%)	3 / 74 (4.05%)	0 / 23 (0.00%)
occurrences (all)	2	4	0
Bad taste			
subjects affected / exposed	1 / 80 (1.25%)	0 / 74 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
Fatigue			
subjects affected / exposed	0 / 80 (0.00%)	0 / 74 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1

Non-serious adverse events	Nose operation + Xylometazoline + Dexpanthenol		
Total subjects affected by non-serious			

adverse events			
subjects affected / exposed	0 / 17 (0.00%)		
Vascular disorders			
Bleeding nose			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Head pressure			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Nasal burning			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Bad taste			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	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