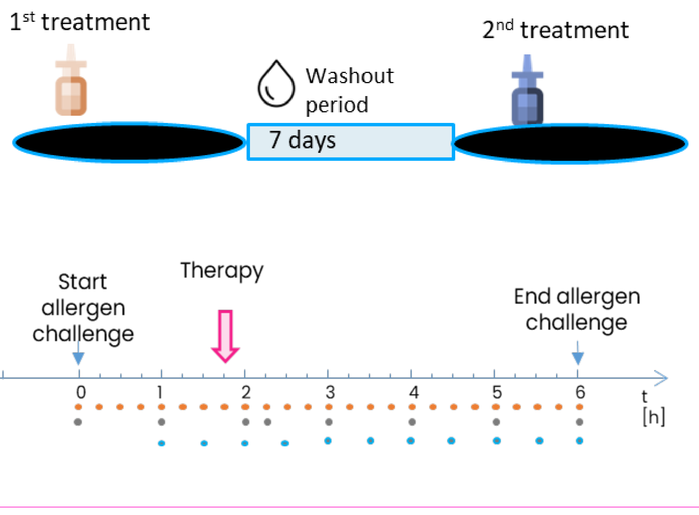
Decongestant effect of treatment with sorbitol-containing Carragelose® nasal spray

Nicole Unger-Manhart[1], Martina Morokutti-Kurz[1], Petra Zieglmayer[2,4], Patrick Lemell[2], Markus Savli[3], René Zieglmayer[2], Eva Prieschl-Grassauer[1]

[1] Marinomed Biotech AG, Korneuburg; [2] Power Project GmbH, Vienna Challenge Chamber Vienna;[3] Biostatistik & Consulting GmbH, Zuerich;[4] Medical University, Vienna

Aim: The objective of the study (NCT04532762) was to evaluate the decongestant effectiveness of a single application of a sorbitol-containing nasal spray in subjects with allergic rhinitis caused by grass pollen.

Clinical trial design:



Treatments:
- Coldamaris akut (1.2mg/ml Carragelose®, 0.4 mg/ml kappa-carrageenan, Sorbitol)
- Coldamaris sine (0.5 % saline)

Endpoints:
- TNSS: nasal congestion, rhinorrhea, itchy nose, sneezing
- Nasal Anterior Airflow (NAA)
- Nasal secretion

Legend:

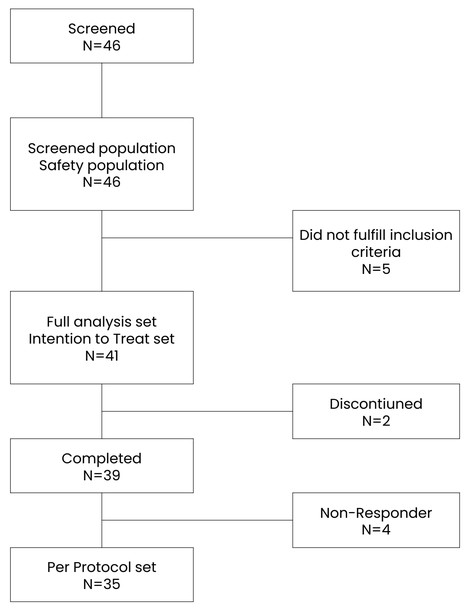
6-hour allergen challenge

Treatment - 1 puff into each nostril

Evaluation TNSS

Measurement of nasal airflow resistance (NAR)

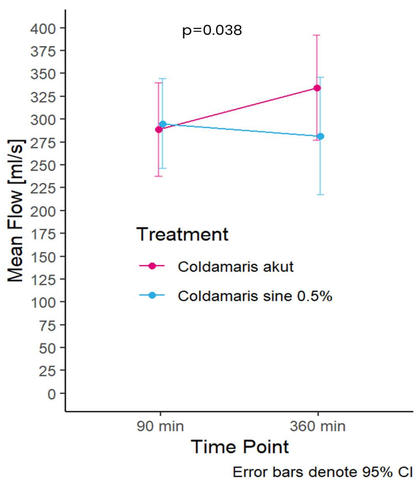
Determination of nasal secretion



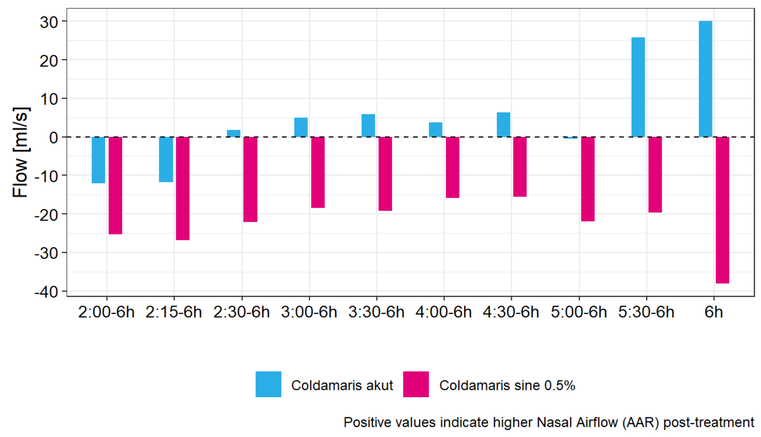
Subjects were exposed to continuous grass pollen in an environmental challenge chamber for six hours. After developing high allergic nasal symptoms, i.e. after 1:45h, subjects received the treatment (1 puff per nostril) resulting in a residual observation period of 4:15h. Subjective symptoms (runny nose, itching, nasal congestion, sneezing) were recorded every 15 minutes, nasal airflow resistance and nasal secretion were assessed every 60 or 30 minutes, respectively.

Results:

NAA by Time and Treatment: Sum Flow, ITT



NAA during different time periods



Subject response of nasal airflow

		Coldamaris akut (360 min - 90 min)	
		better or equal	worse
Coldamaris sine 0.5% (360 min - 90 min)	better or equal	10	3
	worse	13	12

In total, 23 (60%) of the Sorbitol-containing Carragelose® nasal spray treated subjects had an increased anterior nasal airflow whereas in the control group only 13 subjects (34%) had a benefit (p=0.024).

Treatment with Sorbitol-containing Carragelose® nasal spray revealed a continuous increase of nasal airflow over time, while in the control group a continous decline was observed. This led to significantly higher mean anterior nasal airflow compared to saline treated subjects (p=0.038) at 6 hours of allergen challenge.

Nasal secretion

Treatment	Mean Tissue Weight (90 min)	Mean Tissue Weight ([120-360] min)	Mean Tissue Weight Difference ([120-360] - 90 min)	Median Tissue Weight (90 min)	Median Tissue Weight ([120-360] min)	Median Tissue Weight Difference ([120-360] - 90 min)	p-Value of t-Test §	p-Value of Wilcoxon Signed Rank Test §§
Coldamaris akut, ITT	3.99	2.99	-1.00	2.91	2.58	-0.44	0.003	0.005
Coldamaris akut, PPS	3.96	2.93	-1.02	2.87	2.51	-0.47	0.006	0.014
Coldamaris sine 0.5%, ITT	3.07	2.57	-0.50	2.12	1.97	-0.13	0.073#	0.137
Coldamaris sine 0.5%, PPS	2.90	2.45	-0.45	1.94	1.96	-0.08	0.129#	0.218

Normality assumption rejected

§ t-Tests evaluated on mean differences.

§§ Wilcoxon Signed Rank Tests evaluated on median differences. PPS: Per protocol set

After treatment with Sorbitol-containing Carragelose® nasal spray, mean nasal secretion was significantly reduced by 1 g (25%) in average during the 4 hours of grass pollen challenge (p=0.003).

Conclusion:

Application of a Sorbitol-containing Carragelose® nasal spray is beneficial for patients suffering from blocked nose. There were no safety issues during the trial and the nasal spray was well tolerated.