Poster # P5.09

Carragelose®nasal spray is effective in reducing allergic nasal symptoms

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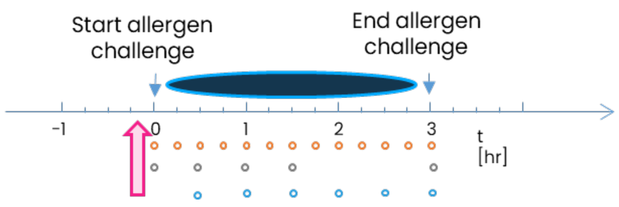
Aim: The objective of the study (NCT04531358) was to evaluate the anti-allergic effectiveness of a single prophylactic application of Callergin nasal spray in subjects with allergic rhinitis caused by grass pollen.

Clinical trial design:



Treatments:
- Callergin (1.2 mg/ml Carragelose® in a buffered solution)
- VisAlpin (0.9% saline)
- No treatment

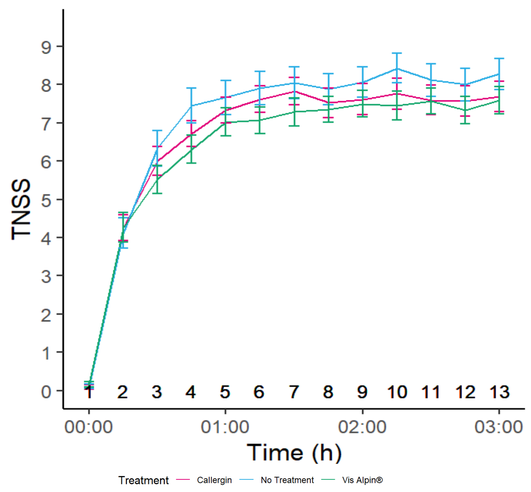
Endpoints:
- TNSS: nasal congestion, rhinorrhea, itchy nose, sneezing
- Nasal Airflow Resistance (NAR)
- Nasal secretion

Legend:
- 3-hour allergen challenge
- Treatment - 1 puff into each nostril
- Evaluation TNSS
- Measurement of nasal airflow resistance (NAR)
- Determination of nasal secretion

In a three-way cross-over double-blinded randomized trial, untreated grass pollen allergic rhinitis volunteers were compared to Callergin and comparator (saline) treated ones (n=42 ITT and PP). Subjects applied one puff of the respective nasal spray five to ten minutes before entering the environmental exposure chamber for 3 hours. After a washout period of 7 days, subjects changed to the next investigation block. Nasal allergy symptoms (runny nose, itching, nasal congestion, sneezing) were recorded every 15 minutes on a 4-point scale and summarized to total nasal symptom score (TNSS). Nasal secretion was assessed by determining tissue weight every 30 minutes.

Results:

Time course of TNSS, FAS



TNSS - Symptom Score differences at 180 minutes

Score	Mean		Mean difference	Median		25%-Percentile		75%-Percentile		p-Value of Wilcoxon Test
	Callergin	No Treatment		Callergin	No Treatment	Callergin	No Treatment	Callergin	No Treatment	
TNSS	7.690	8.286	0.595	8.000	8.500	7.000	7.000	9.000	10.000	0.028
itchy nose	2.000	2.071	0.071	2.000	2.000	2.000	2.000	3.000	3.000	0.520
Nasal congestion	2.286	2.452	0.167	2.000	3.000	2.000	2.000	3.000	3.000	0.076
rhinorrhea	1.833	2.095	0.262	2.000	2.000	1.000	2.000	2.000	3.000	0.013
sneezing	1.571	1.667	0.095	1.500	2.000	1.000	1.000	2.000	2.000	0.387

Continuous grass pollen allergen challenge led to noticeable TNSS in all three investigation groups. The course of TNSS was lower in the groups receiving prophylactic nasal spray treatment. This was reflected in reduced mean TNSS of both treatment groups (6.59±1.93; 6.43±1.77) compared to untreated subjects (6.96±2.30) assessed over the observation period. This trend reached significance at the end of the allergen challenge in the Callergin group (Δ0.596; p=0.028). Most prominent reductions were obtained for rhinorrhea (Δ0.262; p=0.013) and nasal congestion (Δ0.17; p=0.076). Data are presented for Full Analysis Set (FAS).

Nasal secretion 30 min -180 min

	Callergin	Vis Alpin®	No Treatment	No Treatment - Callergin	No Treatment - Vis Alpin®	Callergin - Vis Alpin®
Mean	2.48	2.52	2.85	0.37	0.33	-0.04
SD	2.14	2.27	2.63	1.50	1.65	1.27
Median	1.93	1.69	1.86	0.18	0.34	-0.10
L.Quartile	0.83	0.82	1.18	-0.48	-0.65	-0.59
U.Quartile	3.71	4.23	3.72	0.92	1.17	0.43
Min	0.00	0.01	0.05	-2.72	-3.32	-3.15
Max	7.71	8.25	11.98	4.63	4.55	3.17
N	42	42	42	42	42	42

Mean nasal secretion [g]. FAS population

Callergin - FAS:

The mean difference of No Treatment - Callergin = 0.37, 95% CI [-0.10;0.84], p = 0.119 (Paired t-test).

Vis Alpin® - FAS:

The mean difference of No Treatment - Vis Alpin® = 0.33, 95% CI [-0.18;0.84], p = 0.199 (Paired t-test).

(Callergin - Vis Alpin®) - FAS:

The mean difference of Callergin - Vis Alpin® = -0.04, 95% CI [-0.43;0.36], p = 0.849 (Paired t-test).

Subjective observations are supported by the objective parameter nasal secretion, which was reduced in both treatment groups compared to untreated subjects (p=0.119). There were no safety issues during the study, in total eleven AEs were documented but none led to discontinuation of treatment nor were they critical for patient safety. Furthermore, all AEs were classified as not related.

Conclusion: Callergin nasal spray is effective in reducing nasal allergic symptoms. It is a valuable treatment option for people suffering from allergic rhinitis.