A novel nasal spray formulation of solubilized budesonide (Budesolv 10) promptly improves asthmatic symptoms in patients suffering from grass pollen allergic symptoms induced in an allergen exposure chamber

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Background
Intranasal corticosteroids are considered the most effective pharmacologic treatment for allergic rhinitis with additional benefits on co-existent allergic asthma. Due to poor solubility most of the applied drug is not active in the nasal cavity, but swallowed and transferred into the system. Allergen exposure chambers overcome the limitations of seasonal field studies and allow for controlled exposures to inhalative allergens.

Objectives
Randomized DBPC 3-way crossover pivotal clinical study:

- Suspension Rhinocort Aqua 64 64µg per dose/spray
- Solution Rhinocort 1 Micrograms 10µg per dose/spray
- Therapeutic Equivalence

Methods
75 adult subjects (PP) with grass pollen allergy.

- Allergic symptoms induced during 6-h allergen challenges in the Vienna Challenge Chamber on days 1 and 8.
- nasal (TNSS) symptoms
- asthma/respiratory (TRSS) symptoms
- nasal obstruction (RHM)

Non-inferiority (after 8 days of treatment):
- 95% confidence interval (CI) for difference in means between active treatments.
- Non-inferiority; stated if the upper limit of the CI did not exceed 115% of the reference.

Onset of action (day 1):
- Defined as first time point when the difference in TNSS between active treatment and placebo was p<0.05.
- Onset of action

Results:

- Budesolv 10 enables a fast onset of action after first dose

TRSS of Budesolv 10 on day 1 was superior to Rhinocort

Onset of action of Budesolv 10 compared to Rhinocort or Placebo with respect to TRSS.

Onset of action was calculated using the mean of the three last time points before treatment as baseline. Values with * indicate time points with a significant difference between Budesolv and placebo (*), or Budesolv and Rhinocort (**).

- TRSS of Budesolv 10 on day 8 was equivalent to Rhinocort

Onset of action for TRSS 2.45 hours after initial dose with Budesolv nasal spray only

- TRSS of Budesolv equivalent to Rhinocort on day 8

- Budesolv significantly better than placebo for all parameters evaluated on day 8

Conclusions

References: