



# Rapid Onset Of Action Of A Novel Budesonide Nasal Spray In Grass Pollen Allergic Rhinitis

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## Background:

Intranasal corticosteroids are considered the most effective pharmacologic treatment for allergic rhinitis. Due to poor solubility most of the applied drug is not active in the nasal cavity, but swallowed and transferred into the system<sup>1</sup>.

Allergen exposure chambers<sup>2</sup> overcome the limitations of seasonal field studies and allow for controlled exposures to inhalative allergens.

## Introduction:

This randomized DBPC crossover pivotal study aimed to show the therapeutic equivalence of an aqueous solution of Budesonide (Budesolv 10) to a marketed compound of Budesonide (Rhinocort<sup>®</sup> aqua 64) after 8 days of daily treatment. Furthermore, the onset of action of Budesolv 10 in comparison to Rhinocort<sup>®</sup> aqua 64 was evaluated on Day 1 of each treatment period.

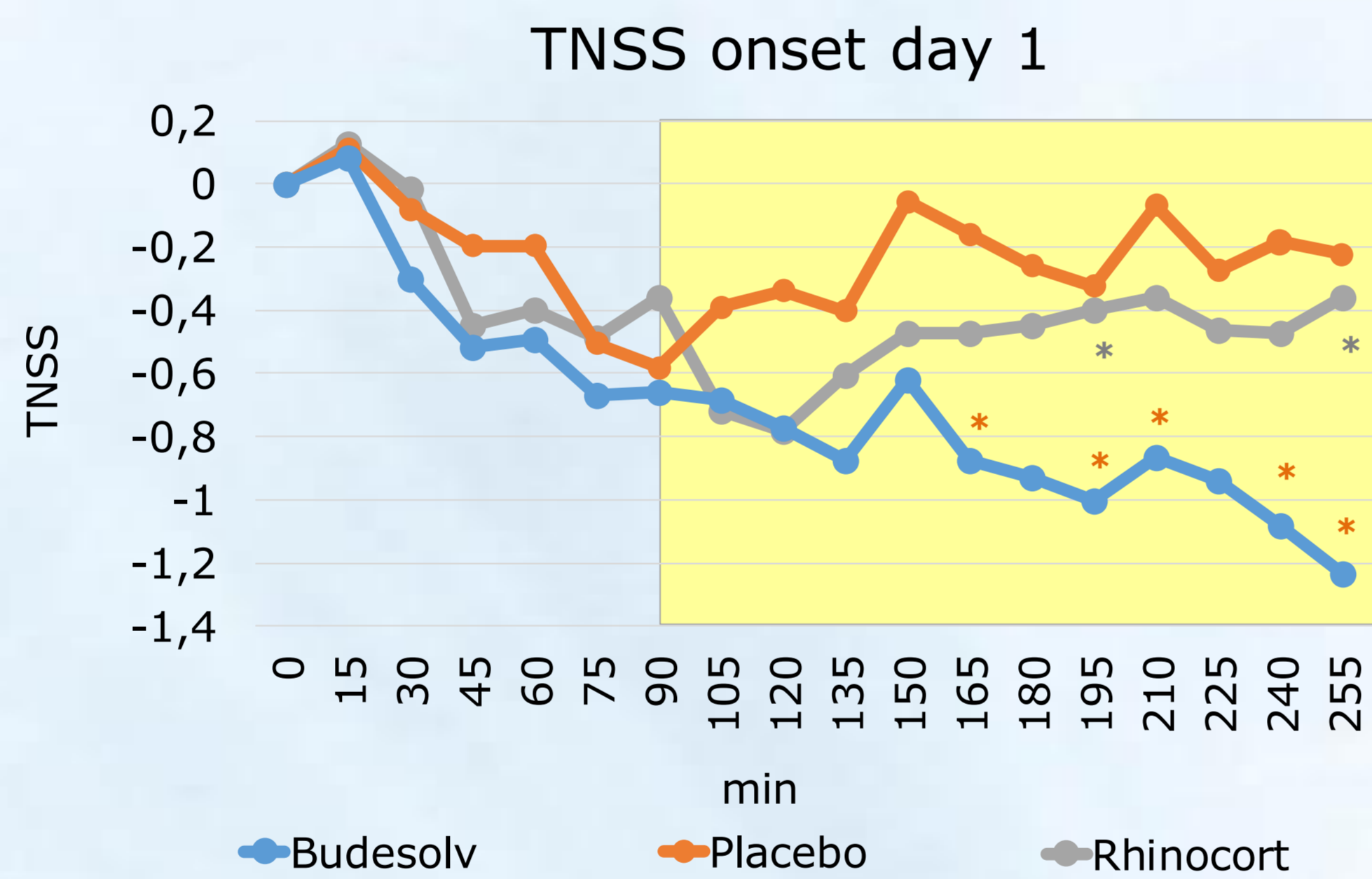
## Methods:

75 adult subjects (PP) with grass pollen allergy were evaluated. Onset of action was defined as first time point when the difference in TNSS change from baseline between active treatment and placebo was  $p < 0.05$ .

## Results:

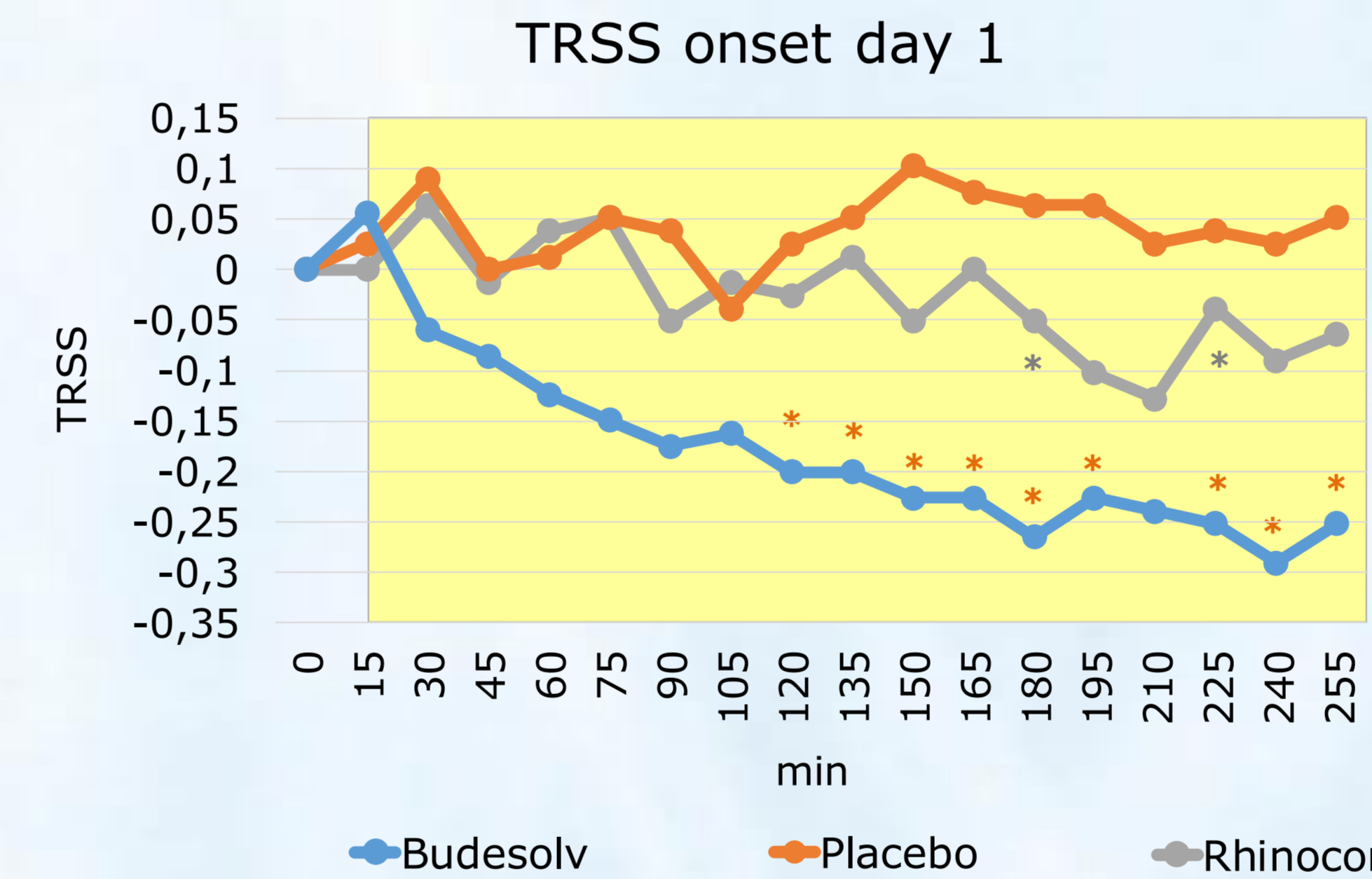
### Budesolv enables a fast onset of action after first dose

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



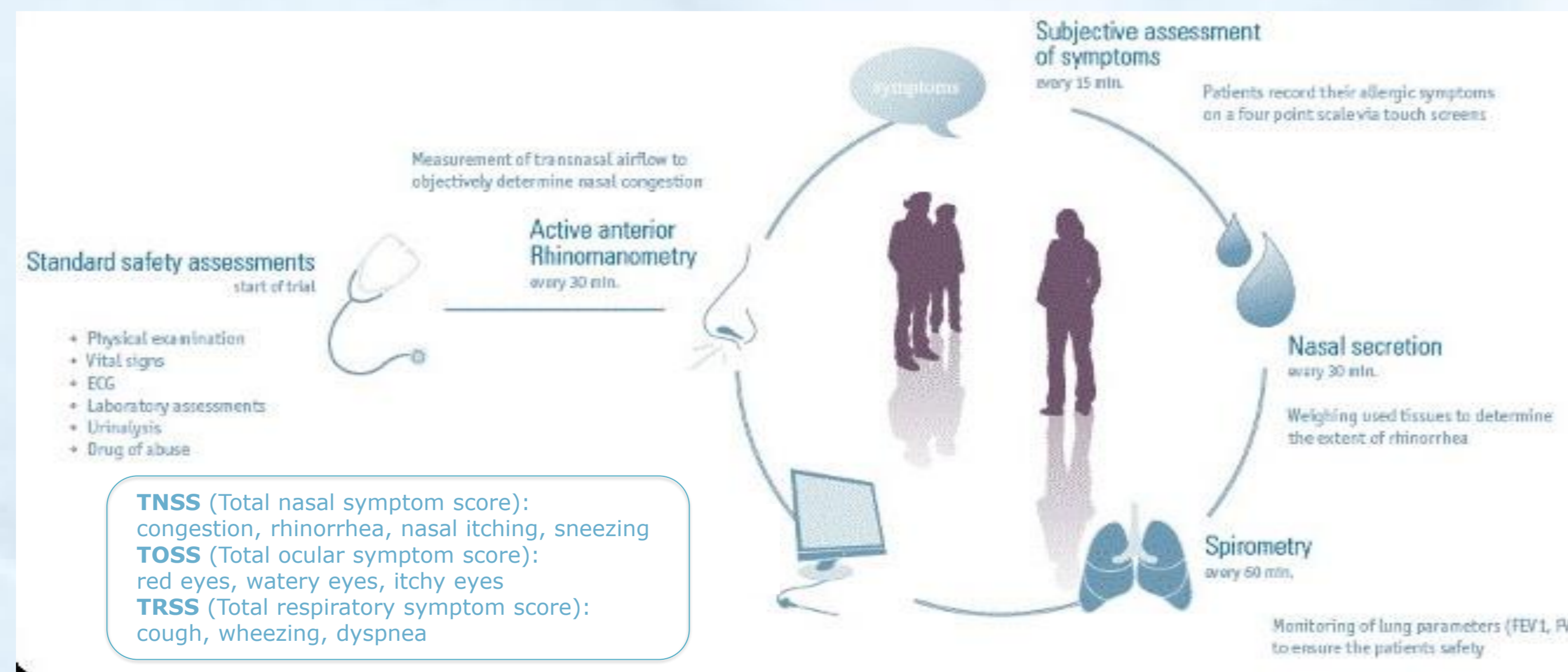
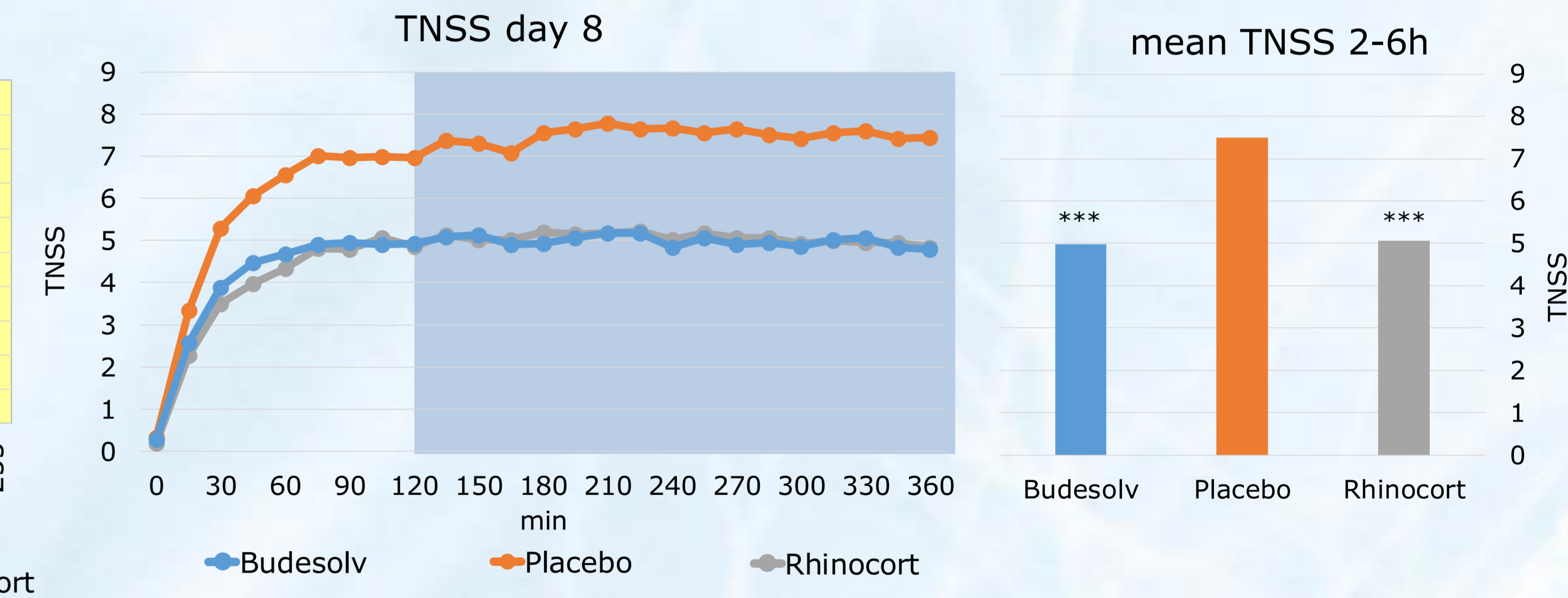
### TRSS of Budesolv 10 on day 1 was superior to Rhinocort

Onset of action of Budesolv 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.



### TNSS of Budesolv 10 on day 8 was equivalent to Rhinocort

Mean TNSS after eight days of treatment with either Budesolv, Rhinocort, or placebo nasal spray over a time period of 6 h (left panel, x-axis). Each data point represents the mean of the values from subjects eligible for the PP population. The blue-shaded area shows the time period applicable for the evaluation of the primary endpoint (2-6h).



## Conclusions

- Onset of action for TNSS 2.45 hours after initial dose with Budesolv nasal spray only
- Onset of action for TRSS 2 hours after initial dose with Budesolv nasal spray only
- TNSS of Budesolv on day 8 equivalent to Rhinocort
- Budesolv significantly better than placebo for all parameters evaluated

## References

- <sup>1</sup>Derendorf H.& Meltzer EO. Allergy 2008;63 (63):1292-1300.
- <sup>2</sup>Day JH et al. Clin Exp Allergy 2006;6:31-59.

