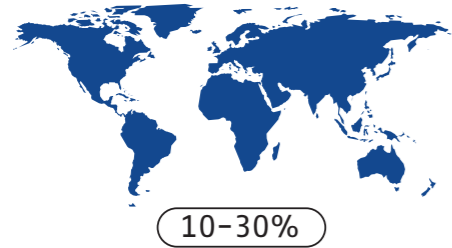




Allergic Rhinitis and air pollution: New clinical evidence with fexofenadine hydrochloride 180 mg

Worldwide prevalence of allergic rhinitis (AR)

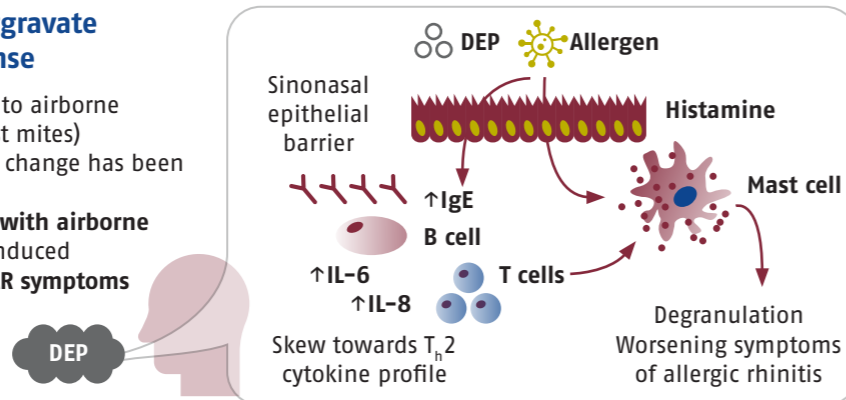


Main allergic rhinitis symptoms

- Rhinorrhoea
 - Sneezing
 - Nasal obstruction
 - Nasal itching
 - Ocular itching
 - Watery eyes
 - Throat itching
-

Diesel exhaust particles (DEP) aggravate allergen-induced allergic response

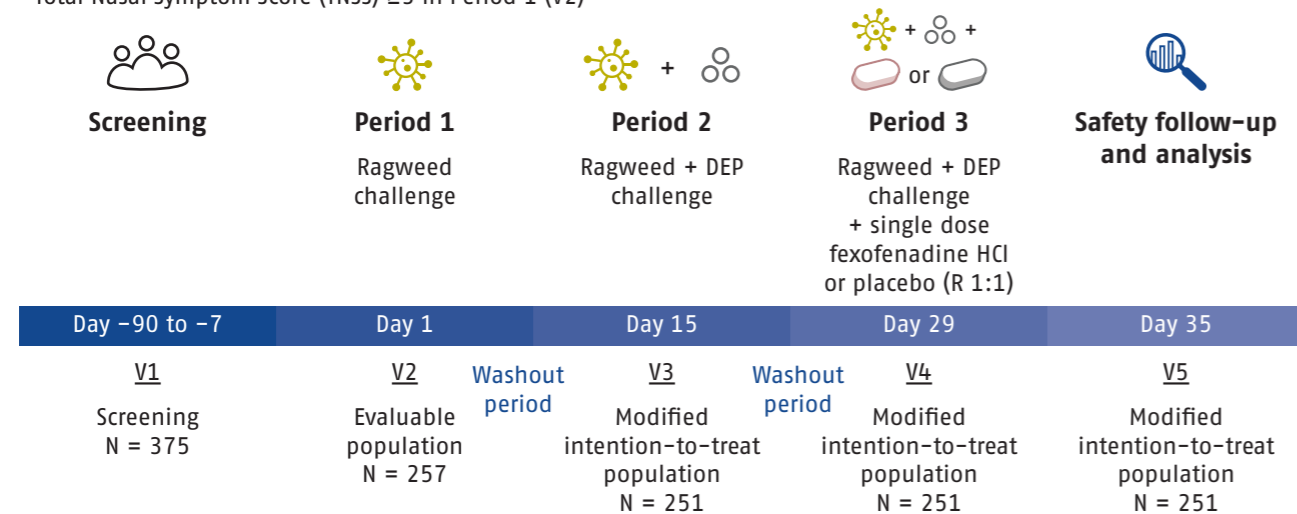
- AR is a **type I hypersensitivity** reaction to airborne allergens, such as pollen (or house dust mites)
- Exposure to **air pollutants** and climate change has been linked to **AR symptom exacerbation**
- DEP, an air pollutant, when **combined with airborne allergen** is able to enhance allergen-induced degranulation, leading to **worsening AR symptoms**



FEXPOLSAR was a phase III, single-centre, sequential, parallel-group, double-blind, randomized study conducted in an environmental exposure unit

Inclusion criteria:

- 2-year history of seasonal allergic rhinitis (SAR) with positive skin prick test to ragweed
- Self-reported history of SAR symptoms aggravated by pollen or air pollutants exposure
- Total Nasal Symptom Score (TNSS) ≥ 3 in Period 1 (V2)



Primary endpoints

Participants graded their **Total Nasal Symptom Score (TNSS)** on a 0–3-point scale over 12-hours from baseline for each Period. TNSS was calculated as the sum of **rhinorrhoea, sneezing, and nasal itching scores**.

First primary objective:
to demonstrate the aggravation of the SAR symptoms caused by DEP exposure



Period 2 vs Period 1

Change in TNSS AUC from baseline to hour 12 (TNSS AUC₀₋₁₂)

Second primary objective:
to evaluate the efficacy of fexofenadine HCl in alleviating symptoms aggravated by DEP presence

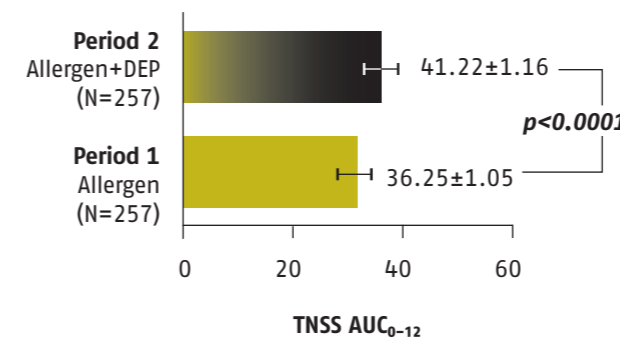


Period 3

Change in TNSS AUC from hour 2 to 12 (TNSS AUC₂₋₁₂)

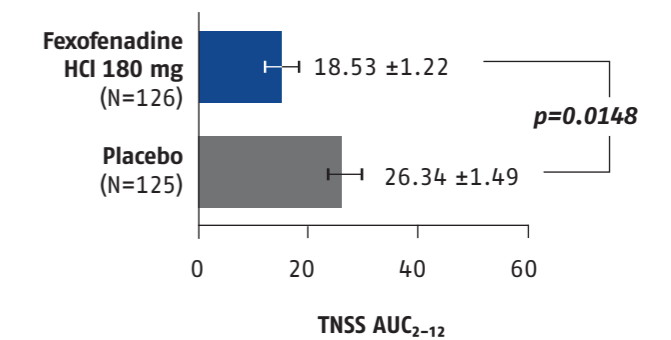
TNSS AUC₀₋₁₂ in Period 1 and 2

A significant **increase** in SAR symptoms from Period 1 to Period 2 was observed



TNSS AUC₂₋₁₂ in Period 3

A significant **decrease** in DEP-aggravated, SAR symptoms was observed with fexofenadine HCl compared with placebo



The proportion of subjects reporting **treatment-emergent adverse events** was higher in the placebo group



15.1%
Placebo group



12.6%
Fexofenadine HCl group

