

## Quality of Life Outcomes with 300 IR Liquid Sublingual Immunotherapy in Allergic Rhinitis: A Systematic Review and Meta-analysis Across Study Designs

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**ADMINISTRATIVE INFORMATION****Support** - Stallergenes Greer.**Review Stage at time of this submission** - Data extraction.

**Conflicts of interest** - D. Di Bona reports receipt of fees from Stallergenes Greer. G. W. Canonica reports research grants, lecturing, or advisory board fees from A. Menarini, Anallergo, Allergy Therapeutics, AstraZeneca, Chiesi Farmaceutici, Faes, Firma, Genentech, Guidotti-Malesci, GlaxoSmithKline, Hal Allergy, Innovacaremd, Novartis, OmPharma, RedMaple, Sanofi-Aventis, Sanofi-Genzyme, Stallergenes Greer, Uriach Pharma, Thermo Fisher Scientific, and Valeas. J. Cognet-Sicé and S. Scurati are employees of Stallergenes Greer, Antony, France. The rest of the authors declare that they have no relevant conflicts of interest.

**INPLASY registration number:** INPLASY202620064

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 February 2026 and was last updated on 20 February 2026.

**INTRODUCTION**

**Review question / Objective** What is the effect of 300 IR liquid sublingual immunotherapy (SLIT) on health-related quality of life in patients with allergic rhinitis compared with baseline and/or placebo?

**Rationale** Quality of life (QoL) is a key patient-reported outcome in allergic rhinitis (AR), yet it has been inconsistently synthesized in allergen immunotherapy (AIT) meta-analyses. Previous reviews have pooled heterogeneous SLIT formulations, allergens, and dosing regimens, limiting product-specific interpretation. International societies (EAACI, WAO) recommend product-based evaluation of AIT evidence.

Therefore, this review focuses exclusively on a single, well-characterized formulation: 300 IR SLIT liquid (Staloral®, Stallergenes Greer).

**Condition being studied** Quality of life (QoL) is a key patient-reported outcome in allergic rhinitis (AR), yet it has been inconsistently synthesized in allergen immunotherapy (AIT) meta-analyses. Previous reviews have pooled heterogeneous SLIT formulations, allergens, and dosing regimens, limiting product-specific interpretation. International societies (EAACI, WAO) recommend product-based evaluation of AIT evidence. Therefore, this review focuses exclusively on a single, well-characterized formulation: 300 IR SLIT liquid (Staloral®, Stallergenes Greer).

## METHODS

### Search strategy

Pubmed, the Web of science, LILACS

The search will combine terms related to: “allergic rhinitis”, “sublingual immunotherapy” OR “SLIT”, “300 IR”, “quality of life” OR “RQLQ”

No language restrictions will be applied.

The final search will be conducted up to 31 August 2025.

**Participant or population** Adults, adolescents, or children diagnosed with allergic rhinitis, sensitized to relevant aeroallergens and treated with 300 IR SLIT liquid.

No restrictions on geographic area or disease severity.

**Intervention** 300 IR SLIT liquid (Staloral®, Stallergenes Greer, Antony, France), administered according to approved schedules (continuous or pre/co-seasonal).

**Comparator** Separate analyses will be conducted for:

1. Before–after comparisons (baseline vs end of treatment)
2. Placebo-controlled RCT comparisons (SLIT vs placebo).

**Study designs to be included** RCTs and NRS.

### Eligibility criteria

Eligible:

Randomized controlled trials (RCTs)

Non-randomized studies (prospective or retrospective)

Cohort studies

Before–after studies

Case series with extractable quantitative data

Excluded:

Studies using mixed SLIT products

Studies without extractable QoL data

Reviews, editorials, case reports.

### Information sources

Electronic databases:

MEDLINE (via PubMed)

Web of Science

LILACS

Manual search of:

Reference lists of included studies

Relevant systematic reviews.

**Main outcome(s)** Health-related QoL using validated instruments (Rhino-Conjunctivitis Quality of Life Questionnaire [RQLQ], mini-RQLQ, or equivalent).

**Additional outcome(s)** Safety (side effects, adverse events; treatment related or -unrelated discontinuations).

**Data management** All retrieved records were imported into Rayyan (<https://www.rayyan.ai>), which was used to manage references, identify and remove duplicates, and support title/abstract and full-text screening, with explicit recording of inclusion and exclusion decisions and reasons. Ouzzani Data extraction was performed independently by two reviewers (DDB, ADB) using a standardized, pre-piloted data extraction form.

There were studies not reporting standard deviations (SDs). For these, we estimated SDs using methods based on summary statistics (minimum, maximum, lower quartile, upper quartile, median, p-values). Weir When standard error (SE) was reported, SD was obtained using the following formula:  $SD = SE \sqrt{n}$ . In some studies, means and SE were obtained from the graphs.

Two reviewers (DDB, ADB), independently, screened titles and abstracts, assessed full texts for eligibility. Disagreements were resolved by consensus adjudication.

### Quality assessment / Risk of bias analysis

RCTs: RoB 2 tool

Non-randomized studies: IHE Case Series Quality Appraisal Checklist

Certainty of evidence will be evaluated using the GRADE approach.

Assessment will be conducted independently by two reviewers.

**Strategy of data synthesis** Meta-analyses will be conducted separately for:

-Before–after comparisons (including active RCT arms)

-Placebo-controlled RCT comparisons

Effect measures:

Standardized mean difference (SMD)

Mean difference (MD) when same scale is used

Statistical model:

Random-effects model (DerSimonian–Laird method)

Heterogeneity:

$I^2$  statistic

Cochran’s Q test.

### Subgroup analysis

Allergen type

Treatment duration

Annual dose

Cumulative dose

Mean age

Asthma prevalence

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Study design  
Meta-regression will be conducted where sufficient data are available.

### **Sensitivity analysis**

Exclusion of high risk-of-bias studies  
Exclusion of influential studies  
Restriction to studies using RQLQ  
Observed vs estimated SD data.

**Language restriction** No language restriction.

**Country(ies) involved** Italy, France.

**Keywords** Meta-analysis; Randomized controlled trial; Rhinitis, allergic; SLIT-liquid; Sublingual immunotherapy, Systematic review.

**Dissemination plans** Results will be submitted to a peer-reviewed journal in the field of allergy and clinical immunology.

### **Contributions of each author**

Author 1 - Danilo Di Bona - DDB developed the concept of this work, did the article search, assessed the articles, and extracted the data. DDB will do all the analyses and write the first manuscript draft.

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Author 2 - Andrea Di Biase - DDB did the article search, assessed the articles, and extracted the data.

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