

# The prevention of respiratory tract infections offered by oral administration of the bacterial lysate-OM-85 is extended to asthma symptoms, exacerbations, and need for oral corticosteroids

<b>Submission date</b> 23/11/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/12/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/12/2025	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Synergistic interactions between allergen sensitization, allergen exposure, and viral infection are detected in asthmatics during exacerbations. This study assessed the effect of the polyvalent chemical bacterial lysate OM-85 on reducing the risk of exacerbations and oral corticosteroids (OCS) use in adults with allergic asthma.

### Who can participate?

Patients aged 18 years and over with moderate to severe bronchial asthma who remain uncontrolled despite adherence to standard of care asthma therapy

### What does the study involves?

Two 3-month treatment courses of co-administration of OM-85. The researchers assessed the medical records of the patients and the e-prescription system of the National Health System of Greece to determine the proportion of patients meeting the definitions of clinical remission at the end of the 12-month observation.

### What are the possible benefits and risks for participating?

Patients treated with OM-85 could improve their asthma control and meet the goals of clinical remission on treatment at the end of the 12-month follow-up. Patients will continue in parallel the standard of care treatment. OM-85 is a well-studied treatment option, approved and available in many countries all over the world, without signals for serious adverse events and/or side effects.

### Where is the study run from?

The study was conducted in specialist care practices in Greece (Athens, Patra and Kalavryta)

### When is the study starting and how long is it expected to run for?

December 2025 to February 2026

Who is funding the study?  
Asthma Clinics Specialist Care Practices (Greece)

Who is the main contact?  
Dr Antonios Christopoulos, [asthmaclinics@outlook.com](mailto:asthmaclinics@outlook.com)

## Contact information

### Type(s)

Principal investigator, Scientific, Public

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## Additional identifiers

## Study information

### Scientific Title

Remission outcomes in severe T2-high asthma with bacterial lysate OM-85 therapy: analysis of the OMRIA study

### Study objectives

The aim of our analysis was to demonstrate that clinical remission on-treatment is a realistic target in difficult-to-treat, moderate to severe T2-high asthma, for those patients treated additionally with the bacterial lysate OM-85.

### Ethics approval required

Ethics approval not required

### Ethics approval(s)

### Primary study design

Observational

### Secondary study design

Cohort study

### Study type(s)

## Health condition(s) or problem(s) studied

Severe bronchial asthma

## Interventions

Post hoc analysis of the OMRIA RWE study (<https://doi.org/10.2147/jaa.s517194>). In this analysis, the researchers used a four-component clinical-remission definition. Patients were required to meet all of the following criteria at the end of the 12-month observational period: i) OCS-free; ii) exacerbation-free; iii) ACT  $\geq 20$ ; and iv) no worsening from baseline in pre-bronchodilator FEV1.

The researchers checked both the medical records of the patients and the e-prescription system of the National Health System of Greece. A post hoc analysis was performed to determine the proportion of patients meeting the individual components of the clinical remission definitions and to appreciate the individual contribution of each component at the end of the 12-month observation. A descriptive analysis of differences in the baseline demographics and clinical characteristics of patients according to their remission status at the end of the observation (i.e. those who met the clinical remission definition compared with those who did not) was also performed to gain insight into the responsive population.

## Intervention Type

Drug

## Phase

Phase III

## Drug/device/biological/vaccine name(s)

Bacterial Lysate OM-85 (PHARMA)

## Primary outcome(s)

1. Remission of bronchial asthma measured using the medical records of patients and the e-prescription system of the National Health System of Greece at 12 months

## Key secondary outcome(s)

## Completion date

15/02/2026

## Eligibility

### Key inclusion criteria

1. Patients  $\geq 18$  years of age
2. A clinical diagnosis of moderate to severe uncontrolled bronchial asthma, despite standard of care (SoC) asthma therapy (appropriate addressing of comorbidities and treatable traits, as well as adherence to GINA step 4 asthma therapy)
3. Patients were required to meet all of the following criteria at the end of the 12-month observational period in order to achieve the clinical remission definition:
  - 3.1. Oral corticosteroid (OCS)-free
  - 3.2. Exacerbation-free
  - 3.3. Asthma Control Test (ACT)  $\geq 20$
  - 3.4. No worsening from baseline in pre-bronchodilator FEV1
4. Have relevant medical records within the prior 12 months

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

85 years

**Sex**

All

**Total final enrolment**

137

**Key exclusion criteria**

Need for maintenance oral corticosteroids (mOCS) for causes other than asthma

**Date of first enrolment**

01/12/2025

**Date of final enrolment**

01/02/2026

**Locations****Countries of recruitment**

Greece

**Sponsor information****Organisation**

Asthma Clinics Specialist Care Practices Greece

**Funder(s)****Funder type****Funder Name**

Asthma Clinics Specialist Care Practices Greece

# Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not expected to be made available