ISRCTN72336993 https://doi.org/10.1186/ISRCTN72336993

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

Submission date
23/11/2025

Recruitment status
No longer recruiting

Registration date
16/12/2025

Overall study status
Ongoing

Last Edited
16/12/2025

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

Contact information

Type(s)
Principal investigator, Scientific, Public

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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 ≥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 ≥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) ≥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