OptimAIR: Towards right care in asthma through point-of-care phenotyping, guidelinebased assessment and management optimalisation using the AsthmaOptimiser in primary care (OptimAIR)

First published: 28/04/2025

Last updated: 28/04/2025

Study Planned

Administrative details

EU PAS number

EUPAS1000000559

Study ID

1000000559

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Chile
- [ ] Spain

Study description

Rationale: Patients with respiratory diseases are mainly treated in primary care, and there remains a need to assess patients' asthma control, risk, trigger avoidance and inhaler technique, and to ensure that patients are prescribed, and take, appropriate treatments according to the latest (international) guidelines, such as the Global Initiative for Asthma (GINA) guideline. Innovative e-health solutions, such as the previously developed AsthmaOptimiser, can guide healthcare professionals through asthma consultations and can facilitate healthcare professionals in optimizing asthma treatment. Structured asthma reviews can also help to uncover opportunities for more personalized management actions.
OptimAIR will provide insight in the prevalence of (un)controlled asthma and opportunities for management optimalisation, specific disease phenotypes and treatable traits in patients at high risk of exacerbations. In addition, participation in this study might reduce the barrier to participate in further clinical trials.

Study design: A prospective study in asthma evaluating point-of-care phenotyping and guidelinebased assessment and management optimalisation using the AsthmaOptimiser in primary care.

Study population: Adult patients with uncontrolled asthma and treated with ICS+LABA.

Study assessment: Each patient will attend a single study visit. During the first part, patient's current asthma control will be assessed using the ACQ-6 and

CAAT, and oscillometry will be performed. In case of uncontrolled asthma and/or abnormal lung function, the patient will continue to the full visit. Patient's current asthma control and management will be assessed using the AsthmaOptimiser, including spirometry, complemented by FeNO measurement, determination of blood eosinophil (bEOS) counts, and post oscillometry. Following the assessment, both patient and their healthcare provider will receive a report with results of the visit, recommended treatment according to the GINA.

Study status

Planned

Research institutions and networks

Institutions

General Practitioners Research Institute (GPRI)

Netherlands

First published: 31/08/2022

Last updated: 31/08/2022

Institution **Laboratory/Research/Testing facility** **ENCePP partner**

Contact details

Study institution contact

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Study timelines

Date when funding contract was signed

Actual: 03/12/2024

Study start date

Planned: 06/05/2025

Data analysis start date

Planned: 05/01/2026

Date of final study report

Planned: 27/03/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

External Sponsored Collaborative Clinical research sponsored by AstraZeneca BV, ESR-24-22707

Study protocol

OptimAIR_master_protocol_v4_15Feb2025 - signed.pdf (2.23 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Evaluating point-of-care phenotyping and guideline-based assessment and management optimalisation

Data collection methods:

Primary data collection

Study design:

The OptimAIR study is a prospective study in asthma evaluating point-of-care phenotyping and
guideline-based assessment and management optimalisation using the AsthmaOptimiser.

Main study objective:

Primary Objective:
Assess the level of asthma control and opportunities for management improvement using the AsthmaOptimiser tool in Argentina, Chile and Spain.

Secondary objectives:
- Gain insights into management changes following the use of AsthmaOptimiser and Oxford asthma attack risk scale (ORACLE) score
- Determine impact of assessment with AsthmaOptimiser on medium term asthma control

Exploratory objectives:
- Assess the population risk for future exacerbation according to the ORACLE score
- Assess impact OptimAIR participation in engagement with clinical trials

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Adult patients with uncontrolled asthma and treated with ICS+LABA

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

700

Study design details

Setting

Patients will be recruited via primary care.

Each patient will attend a single study visit. This visit can be short or full-length, depending on
asthma control and lung function.

Short visit:

During the short visit, patient's current asthma control and status will be assessed using the ACQ-6
and CAAT, and oscillometry will be performed. Based on the outcome of the short visit there are two
options:

1. Well controlled asthma, defined as ACQ-6 score ≤ 0.75 and normal oscillometry (ALDS result: "normal lung function"). The visit is finished. The patient will receive follow-up questionnaires via the Respiratory registry after 3 and 6 months.
2. Uncontrolled asthma, defined as ACQ-6 score > 0.75 OR abnormal lungfunction based on
the ALDS report. The patient will continue with the full visit.

Full visit:

During the full visit, patient's current asthma control and management will be assessed using the
AsthmaOptimiser, including spirometry, complemented by Fraction exhaled nitric oxide (FeNO)
measurement, determination of blood eosinophil (bEOS) counts using point-of-care measurements,
and post oscillometry. Following the assessment, both patient and their healthcare provider will

receive a report with results of the visit, recommended treatment according to the GINA guidance
and future risk according to the ORACLE score. Patients and, where approved by the patient,
treating clinicians receive a list of studies being conducted in their region which the patient might be
eligible for.
Patient follow-up will be conducted after 3 and 6 months using the Respiratory Registry. The
patients will receive an online invitation to fill in a digital questionnaire including questions regarding
their exacerbations during the past 3 months, potential changes in medication use and the CAAT
questionnaire.

Outcomes

Primary objective:
Number and distribution of identified opportunities for treatment and management optimisation (based on Global
Initiative for Asthma (GINA) guidance)

Secondary objectives:
• Number and type of changes made to inhaled medication
• Number of changes of inhaler device made based upon technique optimisation
• Number and type of recommendations made to lifestyle changes (eg smoking cessation)

• Change from baseline in CAAT score after 12 weeks

• Change from baseline in ACQ-6 score after 12 weeks

Exploratory objectives
• Distribution of ORACLE risk score
• Number of patients identified based on ICS use, lung function and biomarkers that would be eligible for non-ICS treatment in clinical trials
• Willingness to participate in interventional clinical trials when approached through OptimAIR visit
• Change in CAAT score in patients eligible and participating in clinical trials versus patients eligible but not participating in clinical trials after 6 months

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Data analysis plan

Mainly descriptive statistics will be used to present the results of the study

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No