Development, validation, utility and economic assessment of a flexible, individualized risk prediction e-tool for exacerbation in patients with severe asthma (Severe asthma risk prediction)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46089

EU PAS number

EUPAS46088

Study ID

46089

DARWIN EU® study

No

Study countries

☐ Singapore

Study description

Individualized prediction of rate of severe exacerbation in patients with severe asthma may improve efficiency of specialist asthma care and the value proposition of advanced treatment options such as therapeutic biologics in asthma. This study aims to develop and validate an individualized risk prediction tool, and implement it via e-health applications (i.e., interactive web and smart phone apps), to inform personalized risk and rate of severe asthma exacerbation at a flexible timepoint. We will further perform decision curve analysis to identify the test-treatment strategies that optimize the clinical utility of this prediction tool, considering prediction accuracy and clinician's risk preference, and identify the cost-effective risk-adaptive intervention strategies that tailor follow-up frequency, specialist care and advanced biologic treatment to an individual asthma patient. To address these study aims, we will retrieve data from three large international clinical trials to develop the model, and use data from the International Severe Asthma Registry and Singapore asthma cohort to externally validate the model and assess its clinical utility. We are optimistic about the long-term demand for the outputs of this research, its potential for sustainability and growth, and its ability to improve patient care and outcomes, and advance Precision Medicine and Digital Health research in respiratory research.

Study status

Planned

Research institutions and networks

Institutions

National University of Singapore

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Institution

Contact details

Study institution contact

WENJIA CHEN

Study contact

wenjiach@nus.edu.sg

Primary lead investigator

WENJIA CHEN

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/01/2022

Study start date

Planned: 31/03/2022

Data analysis start date

Planned: 15/04/2022

Date of final study report
Planned: 31/03/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Singapore Ministry of Education Tier 1 Grant, Optimum Patient Care Global (OPCG)

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 type:

Not applicable

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

1.Develop and validate an individualized prediction model for exacerbations in severe asthma. 2.eHealth implementation through an interactive web app, voice interface, and web Application Programming Interfaces(APIs). 3.Assess the clinical utility and cost-effectiveness of individualized risk prediction model in informing advanced treatment such as generic biologics.

Study drug and medical condition

Medical condition to be studied

Asthma

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

103000

Study design details

Outcomes

Individualized prediction of frequency of severe exacerbations in patients with severe asthma in a time period. Individualized prediction of frequency of serious exacerbations in patients with severe asthma in a time period.

Data analysis plan

First, we will develop a mixed-effect regression model that jointly parameterizes exacerbation rate and severity to predict rate of exacerbation at any time window as well as its severity level, which enables prediction of the number of exacerbations and the risk of having certain number of exacerbations in a given time period. Second, we will externally validate the final prediction model in the ISAR cohort, the endpoints include model calibration (i.e. the agreement between observed and predicted outputs) and model discrimination (i.e. the extent to which the model can distinguish between high- and low-risk individuals). Third, we will implement the individualized prediction models, once validated, into a user-friendly, freely-accessible Web App. Finally, we will perform the decision curve analyses and cost-effectiveness analysis to determine the clinical usefulness and value for money of this prediction tool in guiding asthma specialist referral and prescribing biologics.

Data management

Data sources

Data source(s)

Optimum Patient Care Research Database

Data source(s), other

SSAR Singapore, MENSA United Kingdom, DREAM United Kingdom, LAQ Switzerland

Data sources (types)

Other

Data sources (types), other

Randomized controlled clinical trials

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