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Seasonal asthma exacerbation prevention with depemokimab

Submission date
15/05/2025

Recruitment status
Not yet recruiting

Registration date
15/07/2025

Overall study status
Ongoing

Last Edited
15/07/2025

Condition category
Respiratory

[X] 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
People with asthma can take medication to control their symptoms. Despite this, asthma attacks (exacerbations) can still happen, particularly in the autumn and winter months. People may need to visit emergency departments for treatment, and sometimes stay in hospital. During autumn and winter, hospitals in the UK are under high pressure to provide care for seasonal illnesses (also referred to as winter pressures) and research is needed to reduce this.
The aim of this study is to see if a new medicine called depemokimab can prevent asthma attacks over the autumn/winter period, when taken alongside current asthma medication. Depemokimab is a monoclonal antibody (also known as a biologic) and one dose can be given to treat people for up to six months. It is an unlicensed drug, which means trials are being conducted to collect the information needed to become a licensed medicine in the UK. All the studies conducted so far have shown that it is safe to be given at this dose. To see if the medicine works in this group of patients, it will be compared with a placebo (dummy medicine).

Who can participate?
Adults (aged 18 years and above) who have suffered from seasonal asthma exacerbations will be invited to take part in the study around September 2025.

What does the study involve?
Participants will be checked to make sure it is safe & suitable for them to take part. This involves tests/assessments at a hospital. A computer program is then used to decide which group they will enter. Half of the participants will receive one dose of the drug; the other half will be given one dose of a placebo. The drug/placebo will be injected under the skin. The study is blinded, which means neither the participants or the study team will know which group they are in. They will attend follow-up visits over eight months (some at hospital, others via telephone) to check how they are feeling and if they have experienced any asthma attacks. The study will recruit 170 participants from eight hospitals across England and Scotland.

What are the possible benefits and risks of participating?
It is possible that depemokimab will reduce the asthma attacks experienced by participants during the autumn and winter time. However, we cannot say this for certain until we have completed this study and future research. Participants receiving the placebo injection will not be

given a medicine that could potentially help with asthma attacks. Participants may not directly benefit from taking part in this study, but the information gained will help to improve the treatment of patients with this condition in the future.

Where is the study run from?
Guy's Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2025 to June 2026

Who is funding the study?
GlaxoSmithKline (UK)

Who is the main contact?
Prof. David Jackson, david.jackson@nhs.net

Contact information

Type(s)
Principal Investigator

Contact name
Prof David Jackson

Contact details
School of Immunology & Microbial Sciences
5th Floor, Guy's Hospital
London
United Kingdom
SE1 9RT
+44 (0)7737152154
david.jackson@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1012131

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
3645 ASCEND

Study information

Scientific Title

SeASonal asthma exaCErbation preveNtion with Depemokimab (ASCEND)

Acronym
ASCEND

Study objectives
Primary objective:
To evaluate the efficacy of a single dose of depemokimab compared to placebo on preventing seasonal (autumn/winter) asthma exacerbations in participants with moderate-to-severe asthma.

Secondary objectives:
1. To evaluate the efficacy of depemokimab on patient-reported asthma control.
2. To evaluate the efficacy of depemokimab on preventing seasonal asthma exacerbations resulting in visits to the emergency department and/or hospitalisations.
3. To evaluate the effect of depemokimab on clinic visit post-bronchodilator FEV1.
4. To evaluate the efficacy of depemokimab on patient-reported quality of life.
5. To evaluate the efficacy of depemokimab on preventing asthma exacerbations in participants with blood eosinophil count ≥300 cells/μL at randomisation.
6. To evaluate the efficacy of depemokimab on preventing asthma exacerbations in participants with FeNO ≥50 ppb at randomisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending approval; ref: 25/EM/0126

Study design
Randomized placebo-controlled double-blind study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Safety, Efficacy

Participant information sheet

Health condition(s) or problem(s) studied
Moderate-to-severe asthma

Interventions

Participants will be randomized at baseline in a 1:1 ratio, in addition to standard of care therapy, to receive:
1. Depemokimab 100 mg dose administered as a single subcutaneous injection
2. Matching placebo administered as a single subcutaneous injection

All participants will be followed up at weeks 4, 10, 18, 26 and 35 post-dosing.

Randomisation will take place using the online MedSciNet system upon confirmation of eligibility. All site team members – PI, research fellows, research nurses and pharmacy teams – will be blinded to allocation.

Intervention Type
Drug

Pharmaceutical study type(s)
Prophylaxis

Phase
Phase III

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

Primary outcome measure
Asthma exacerbations – annualised rate (AER) – measured at week 26

Secondary outcome measures
1. Patient reported asthma control measured using Asthma Control Questionnaire (ACQ-5) at week 26
2. Asthma-related emergency department visits and/or hospitalisations measured at week 26
3. Forced expiratory volume (FEV1) (severity and reversibility of airflow obstruction) – post bronchodilator – measured at week 26
4. Patient-reported quality of life related to asthma measured using the Asthma Quality OF Life Questionnaire (AQLQ (S)=12) at week 26
5. Asthma exacerbations in participants with blood eosinophil count ≥300 cells/μL at randomisation – annualised rate (AER) – measured at week 26
6. Asthma exacerbations in participants with FeNO ≥50 ppb at randomisation – annualised rate (AER) – measured at week 26

Overall study start date
13/05/2025

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Ability to provide written informed consent
2. Adults (≥18 years at the time of randomisation)

3. Physician-diagnosed asthma with duration of ≥12 months (based on the BTS/NICE 2024 Guidelines) at the time of randomisation)
4. Treatment with medium or high-dose ICS/LABA therapy (MART is permitted)
5. Documented history of ≥1 asthma exacerbation requiring the use of systemic corticosteroids (oral or parenteral) during each of the previous 2 autumn/winter seasons (i.e. autumn/winter 2023-24 and 2024-25) or 1 asthma-related hospitalisation in the previous autumn/winter (2024-25). The autumn and winter seasons extend from 15th September to 15th March.
6. The most recent exacerbation must have been whilst the patient was prescribed medium or high dose ICS/LABA
7. Post-bronchodilator FEV1 ≥60% predicted at randomisation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
170

Key exclusion criteria
1. Known history of systemic hypersensitivity or anaphylaxis to any biologic therapy
2. Regular use of immunosuppressive medication (including but not limited to maintenance daily prednisolone, hydrocortisone, azathioprine, or weekly methotrexate)
3. Receipt of any licensed biologic drug (eg, omalizumab, mepolizumab, benralizumab, reslizumab, dupilumab, tezepelumab, or other monoclonal antibody) or any investigational biologic for asthma within 24 months prior to randomization
4. Scheduled elective surgery or other procedures requiring general anaesthesia during the trial
5. Any unstable or significant other medical condition which, in the opinion of the Investigator, may either put the participant at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial

Date of first enrolment
22/08/2025

Date of final enrolment
10/10/2025

Locations

Countries of recruitment
United Kingdom

Study participating centre
Not provided at time of registration
United Kingdom
-

Sponsor information

Organisation
King's College London

Sponsor details
KHP CTO, Floor 16
Tower Wing
Guy's Hospital
Great Maze Pond
London
England
United Kingdom
SE1 9RT
+44 (0)207 1885732
Qm.khpcto@kcl.ac.uk

Sponsor type
University/education

Website
https://www.kcl.ac.uk/index

ROR
https://ror.org/0220mzb33

Organisation
Guy's and St Thomas' NHS Foundation Trust

Sponsor details
Guy’s Hospital
Great Maze Pond
London
England
United Kingdom
SE1 9RT
+44 (0)207 1885732
Qm.khpcto@kcl.ac.uk

Sponsor type

Hospital/treatment centre

Website
https://www.guysandstthomas.nhs.uk/

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Submission to regulatory authorities
5. Anonymised data may be shared with external collaborators, subject to any commercial IP sensitivities with the IMP.

Anonymised study results will be disseminated through the publication of journal articles, presentation at relevant conferences, and submission of the Final Study Report to the relevant regulatory bodies.

Intention to publish date
30/06/2027

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date