A double blind (sponsor open) placebo-controlled, stratified, parallel group study to evaluate the efficacy and safety of repeat doses of GSK3772847 in participants with moderate to severe asthma with allergic fungal airway disease (AFAD) (207972)

Published: 17-04-2018
Last updated: 25-03-2025

Primary:To evaluate the efficacy of 3 doses of GSK3772847 (administered every 4 weeks) compared with placebo in moderate to severe asthma participants with allergic fungal airway disease (AFAD) who are currently on Standard of Care (SoC) Secondary:...

Ethical review	Approved WMO
Status	Completed
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON46085

Source
ToetsingOnline

Brief title
207972

Condition

- Bronchial disorders (excl neoplasms)

Synonym
bronchial asthma; asthma

Research involving
Human

Sponsors and support

Primary sponsor: GlaxoSmithKline
Source(s) of monetary or material Support: GlaxoSmithKline BV

Intervention

Keyword: asthma, fungal allergy, GSK3772847, placebo

Outcome measures

Primary outcome

Change from baseline (Week 0) in blood eosinophils over time. Change from

baseline (Week 0) in fractional exhaled nitric oxide (FeNO) over time

Secondary outcome

Serum concentrations of GSK3772847. Serum levels of free and total soluble ST2.

anti-GSK3772847 antibodies. ACQ-5 and AQLQ questionnaires. Change from baseline

in FEV1. Adverse events.

Study description

Background summary

GSK3772847 (formerly CNTO 7160, in-licensed from Janssen) is a human IgG2 sigma isotype antibody that binds to the interleukin-33 receptor. Blockade of the IL-33 receptor presents a potential novel treatment for severe asthma as an add-on to standard of care. Agents targeting this mechanism could be expected to have effects on both T2-driven and non-T2-driven disease.
Allergic fungal airway disease (AFAD) is defined as IgE sensitisation to particularly Aspergillus fumigatus. Clinical data suggest increased IL-33 levels in bronchoalveolar fluid and endobronchial biopsy at baseline disease of children with severe asthma with fungal sensitization. and in lung tissue samples from patients with allergic bronchopulmonary aspergillosis. Recent data reported an association between IgE sensitisation to fungi like Aspergillus fumigatus and the presence of lung damage as demonstrated by high-resolution

computed tomography scanning in moderate to severe asthma. This study aims to evaluate the effects of GSK3772847 in moderate to severe asthma participants with AFAD on top of standard of care.

Study objective

Primary:
To evaluate the efficacy of 3 doses of GSK3772847 (administered every 4 weeks) compared with placebo in moderate to severe asthma participants with allergic fungal airway disease (AFAD) who are currently on Standard of Care (SoC)
Secondary:
PK. PD. Antibodies against GSK3772847. Health status. Lung function. Safety and tolerability.

Study design

Double blind (sponsor open) placebo-controlled, stratified, parallel group study to evaluate safety and efficacy of GSK3772847 (3 IV infusions 50 mL, each 4 weeks apart).
Randomization 1:1 to GSK3772847 and placebo on top of standard treatment.
2 weeks run-in on standard treatment. Study treatment 12 weeks. Follow-up 12 weeks.
46 subjects.

Intervention

Treatment with GSK3772847 or placebo on top of standard therapy.

Study burden and risks

Risk: Adverse events of GSK3772847.
Burden:
8 visits in 28 weeks.
Complete physical examination: once.
Blood tests: 7 visits, 380 mL in total.
Pregnancy test: 6 times (urine or blood).
Sputum induction: 2 times.(if failed: test should be repeated at next occasion; so at most 4 times in total).
ECG: 5 visits.
Diary: daily, rescue medication, change in medication, medical problems.
Questionnaires (1-2): 6 times.
FeNO test: 6 times.
Lung function: 6 times.
Optional blood sample (6 mL) for genetic research.

Contacts

Public
GlaxoSmithKline

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Males and females >=18 years of age.
• Documented diagnosis of moderate to severe asthma for >=12 months.
• Treated with inhaled corticosteroid and long-acting beta-2-agonist for at least 4 months (>=500 ug/day fluticasone propionate or equivalent).
• Pre-bronchodilator FEV1 35-79% of predicted.
• FeNO >=25ppb at Screening.
• ACQ-5 score >=1.5 at Screening
• Blood eosinophils >=300 cells/microliter at Screening.
• Evidence of allergic fungal airway disease. See protocol page 38 for details.
• Female participants of childbearing potential: see protocol page 38-39 for details..

Exclusion criteria

• Concurrent respiratory diseases. See protocol page 39 for details.
• History of chronic or recurrent non-pulmonary infectious disease or ongoing non-pulmonary infection. See protocol page 39 for details.
• Serious infection within 8 weeks of enrolment. See protocol page 39 for details.
• Clinically significant organic heart disease. See protocol page 39 for details.
• Eosinophilic diseases. See protocol page 40 for details.
• Prior or concomitant therapy as in Table 2 on protocol page 40.
• Abnormal and clinically significant ECG findings as in Table 3 on protocol page 41.
• Current smokers or former smokers with a smoking history >=10 pack years.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	09-10-2018
Enrollment:	4
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	GSK3772847
Generic name:	GSK3772847

Ethics review

Approved WMO Date:	17-04-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-07-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-11-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-12-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-02-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-02-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2017-003544-20-NL
CCMO	NL65598.100.18
Other	www.gskclinicalstudyregister.com onder studieID 207972

Study results

Date completed: 25-04-2019

Results posted: 15-01-2021

First publication
23-12-2020

URL result
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

Internal documents
File