A 52 week, multi-center, randomized, double-blind placebo-controlled study to assess the clinical efficacy and safety of ligelizumab (QGE031) in decreasing the sensitivity to peanuts in patients with peanut allergy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON52165

Source
ToetsingOnline

Brief title
CQGE031G12301

Condition

- Allergic conditions

Synonym
food allergy, peanut allergy

Research involving

Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma B.V. (sponsor/verrichter van dit onderzoek)

Intervention

Keyword: Allergy, ligelizumab, Peanut

Outcome measures

Primary outcome

To evaluate the efficacy of ligelizumab 240 mg and 120 mg (SCq4w) compared to placebo, as measured by the proportion of participants who can tolerate a single dose of >= 600 mg (1044 mg cumulative tolerated dose) of peanut protein without dose-limiting symptoms during the double blind placebo controlled food challenge (Section 16.4, Table 16-7) at Week 12

Secondary outcome

Key:

-To evaluate the efficacy of ligelizumab 240mg and 120mg (SCq4w), compared to placebo, as measured by:

--the proportion of participants who can tolerate a single dose of >= 1000mg (2044mg cum. tolerated dose) of peanut protein without dose limiting symptoms during the double blind placebo controlled food challenge (DBPCFC) at w12

--the proportion of participants who can tolerate a single dose of 3000mg (5044mg cum. tolerated dose) of peanut protein without doselimiting symptoms during the DBPCFC at w12

--the maximum symptom severity at any single challenge dose up to and

including 1000mg of peanut protein during the DBPCFC at w12

-To evaluate the efficacy of 8 weeks of placebo treatment followed by 4 weeks of ligelizumab 120mg and 240mg (SCq4w) treatment compared to 12 weeks of placebo treatment, as measured by the proportion of participants who can tolerate a single dose >=1000mg of peanut protein without dose-limiting symptoms during the DBPCFC at w12

Other 2ndary objectives:

-listed in the clinical study protocol

Study description

Background summary

Currently, standard treatment for food allergy is limited to strict avoidance of the allergen and emergency medication in case of accidental exposure. However, accidental exposures of food-sensitive individuals to the very antigen they are trying to avoid occur frequently.
Ligelizumab is a new agent, whose efficacy and safety in peanut allergy is being investigated. Ligelizumab has not yet been approved ("registered") as a medicine by the Dutch government. Doctors may not prescribe it to patients. For registration, research with patients is needed. The results of this study will be used for this.
More than 2,000 patients with various conditions, including persistent hives and asthma, have so far been treated with ligelizumab in trials. The effects of ligelizumab on peanut allergy have not been studied previously. We therefore do not yet know whether it works in this condition.
Ligelizumab is a so-called monoclonal antibody. This is a protein that is made in the laboratory to have a specific effect in the body. It is similar to some proteins that are made by the body itself.

Study objective

The purpose of this Phase 3 study is to evaluate the safety and clinical efficacy of ligelizumab 240 mg and 120 mg given subcutaneously (s.c.) every 4 weeks (q4w) to ensure protection against allergic reaction by decreasing the

sensitivity to oral peanut allergen in participants aged 6 to 55 years with peanut allergy, compared to placebo. Data from this study, as well as data from an additional Phase 3 study assessing two other major food allergens (milk and egg), will support the registration of ligelizumab in food allergy to protect participants against allergic reactions due to an accidental exposure irrespective of the causative food allergen(s).

Study design

This is a 52-week, Phase 3 multi-center, randomized, double-blind and placebo-controlled study to assess the safety and clinical efficacy of two dosing regimens of ligelizumab (240 mg and 120 mg) SCq4w (subcutaneous injection every 4 weeks) in participants with a medically confirmed diagnosis of IgE-mediated peanut allergy. Approximately 486 participants will be randomized to ligelizumab 240 mg, ligelizumab 120 mg, or placebo (5 treatment arms, randomization ratio of 2:2:2:2:1) for the double-blind placebo-controlled treatment period (up to Week 12). Participants initially assigned to the 8-week placebo arms will receive the first dose of blinded ligelizumab treatment at the Week 8 visit. Participants initially assigned to the 16-week placebo arm will receive the last dose of placebo before the DBPCFC at week 12 and the first dose of blinded ligelizumab treatment at the Week 16 visit.
Participants will be stratified based on region, total IgE at baseline (<350 IU/ mL; >=350 IU/ mL) and age (6-11y, 12-17y, and 18-55y). Approximately the same number of participants will be randomized into each age group.

Intervention

* Ligelizumab 240 mg sc q4w
* Ligelizumab 120 mg sc q4w
* Placebo 0 mg sc q4w

Study burden and risks

- 14 s.c. injection every 4 weeks
- physical exam 8x
- vital signs: 24x
- length and/or weight measurments: 7x
- Blood draws: 8x , maximal 45 ml per visit
- Urinalysis: 5x
- stool sample examination: 2x from 3 different bowel movements
- ECG: 4x
- Scin Prick Test: 4x
- double blind placebo controlled food challenge: 3x
- Spirometry in co-morbid asthma only: 7x

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

- Male or female participants who are >= 6 and <= 55 years of age at the time of signing informed consent/assent.
- Documented medical history of allergy to peanuts or peanut-containing foods.
- Positive peanut-specific immunoglobulin E (peanut sIgE), >= 3.5 kUA/L at Screening visit 1 (Screening 1)
- Positive skin prick test (SPT) for peanut allergen at Screening 1 defined as an average diameter (Longest diameter and mid-point orthogonal diameter) >= 4 mm wheal compared to saline control.
- A positive peanut DBPCFC at baseline (Screening Visit 2, Part 1 and Part 2 DBPCFC) defined as the occurrence of dose-limiting symptoms at a single dose <=

100 mg of peanut protein.
Eligibility to proceed with the DBPCFC requires fulfillment of all other eligibility criteria.
- Participants must weigh >= 20 kg at Screening 1.

Exclusion criteria

- Total IgE >2000 IU/mL at Screening 1.
- History of severe or life-threatening hypersensitivity event needing an ICU admission or intubation within 60 days prior to baseline DBPCFC (Screening visit 2).
- Participants with uncontrolled asthma (according to GINA guidelines, GINA 2020) who meet any of the following criteria:
- FEV1 <80% of subject's predicted normal value at Screening visit 1
- One hospitalization for asthma within 12 months prior to Screening visit 1

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2022
Enrollment:	14
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ligelizumab
Generic name:	Ligelizumab

Ethics review

Approved WMO Date:	21-12-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	17-03-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	22-04-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-05-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-07-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-08-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-10-2022
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO Date:	08-11-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-04-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-04-2023
Application type:	Amendment
Review commission:	METC NedMec

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	EUCTR2020-005339-56-NL
ClinicalTrials.gov	NCT04984876
CCMO	NL78859.041.21