A multi-center, double-blinded and open-label extension study to evaluate the efficacy and safety of ligelizumab as retreatment, self-administered therapy and monotherapy in Chronic Spontaneous Urticaria patients who completed studies CQGE031C2302, CQGE031C2303, CQGE031C2202 or CQGE031C1301

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The purpose of the study is to establish the efficacy and safety of ligelizumab in treating adult and adolescent subjects with chronic spontaneous urticaria. This study also looks how:• further treatment of ligelizumab works following ligelizumab or...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Angioedema and urticaria
Study type	Interventional

Summary

ID

NL-OMON52548

Source
ToetsingOnline

Brief title
CQGE031C2302E1

Condition

- Angioedema and urticaria

Synonym
Chronic sponataneous Urticaria, Rash

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: Biological, CSU, Extension study, Ligelizumab

Outcome measures

Primary outcome

To evaluate the efficacy of retreatment with ligelizumab 72 mg or 120 mg q4w in subjects previously treated in the core studies (CQGE031C2302/CQGE031C2303)

Secondary outcome

Objective 1: To describe the efficacy of ligelizumab 72 mg or 120 mg q4w in achieving complete control of chronic spontaneous urticaria (CSU) at Week 12 when used as retreatment for subjects previously treated in the core studies (CQGE031C2302/CQGE031C2303)

Objective 2: To describe the efficacy of ligelizumab with respect to a reduction from extension study baseline in the UAS7 and its components (weekly itch severity score (ISS7) and weekly hives severity score (HSS7) at Week 12 in all subjects receiving the same dose regimen as in the core studies, i.e. 72 mg or 120 mg q4w.

Objective 3: To describe the efficacy of ligelizumab in achieving an angioedema-free period at Week 12 in all subjects receiving the same dose regimen as in the core studies, i.e. 72 mg or 120 mg q4w

Objective 4: To describe the efficacy of ligelizumab in achieving Dermatology Life Quality Index (DLQI) = 0-1 at Week 12 when used as retreatment for all subjects receiving the same dose regimen as in the core studies, i.e. 72 mg or 120 mg q4w

Objective 5: self-administration efficacy: To describe the efficacy of ligelizumab in the treatment of CSU, 12 weeks after starting self-administration

Objective 6: To assess the safety and tolerability of ligelizumab in all subjects (pre-filled syringes and self administration).

Study description

Background summary

Ligelizumab (QGE031) is a newer humanized immunoglobulin G (IgG)-type monoclonal antibody that binds to human IgE with higher affinity than omalizumab. Upon binding to specific epitopes in the C3 region of IgE, ligelizumab is able to block the interaction of IgE with both the high and low affinity IgE receptors (Fc*RI and Fc*RII). IgE plays a role in allergic reactions. The purpose of this extension study (up to 104 weeks of treatment and up to 52 weeks of posttreatment follow-up) is to establish efficacy and safety of ligelizumab (QGE031) 120 mg s.c. (every 4 weeks).

Study objective

The purpose of the study is to establish the efficacy and safety of ligelizumab in treating adult and adolescent subjects with chronic spontaneous urticaria.

This study also looks how:
• further treatment of ligelizumab works following ligelizumab or omalizumab treatment in the preceding studies.
• self-administration of ligelizumab works outside of the clinic setting.

• ligelizumab works without the background medication (in a small group of participants)
• if treatment for a longer time with ligelizumab results in improvement or recovery of the disease.

Study design

This is a phase III multi-center, double-blinded and open-label extension study. As depicted in Figure 3-1, page 21 of the protocol, the study consists of 5 distinct periods.
• Screening period, duration 1 to 4 weeks;
• First observation period, duration up to 36 weeks;
• Treatment period, duration of 2 years (104 weeks);
• Second observation period, duration up to 52 weeks;
• Post-treatment follow-up period, duration of 12 weeks or 52 weeks.

The minimum duration of a subject*s stay in the study without early discontinuation is approximately 37 weeks: 1 week screening plus 36 weeks in first observation period until the subject exists the study without a relapse.

The maximum duration of a subject*s stay in the study without early discontinuation is approximately 208 weeks: 4 weeks screening, 36 weeks in first observation period, 52 weeks in first half of the treatment period, 52 weeks in the second half of the observation period, 52 weeks in second half of the treatment period and 12 weeks in the follow-up period until the subject exists the study.

Intervention

For subjects rolling over from the core study CQGE031C2303 (NLD)

Blinded treatment period (Week 0, 4 and 8):
* Ligelizumab 120 mg arm: 1 injection of 1.0 mL ligelizumab (120 mg/mL) s.c. q4w
* Ligelizumab 72 mg arm: 1 injection of 0.6 mL ligelizumab (120 mg/mL) vial s.c. q4w
Open-label treatment period (Week 12 through Week 52):
* Ligelizumab 120 mg arm: 1 pre-filled syringe injection of 1.0 mL ligelizumab s.c. q4w

Study burden and risks

• s.c. injectie every 4 weken
• Physical examination
• Length (only for participants < 18) and weight measurments
• Blood tests
• Optional blood tests for biomarkers (only for participants 18 years and

older)
• Urine sampling (for female participants pregnancy tests)
• Stool evaluation
• eDiary completion (2x a day)
• Questionnaires
• Electrocariogram

See protocol page 56-65 for the full schedule of assessment in the 5 distinct periods of the study. The number of assessements to be completed depends on the visits the subject completes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Written informed consent

2. Subjects who successfully completed all of the treatment period and the follow-up period in any of the following studies: CQGE031C2302, CQGE031C2303, CQGE031C2202 or CQGE031C1301
3. Male and female, adult and adolescent subjects >=12 years of age
4. Willing and able to complete a daily symptom eDiary for the duration of the study and adhere to the study visit schedule

Exclusion criteria

1. Use of investigational drugs, other than those in use in the preceding studies, at the time of enrollment
2. Use of omalizumab within 16 weeks of Screening
3. History of hypersensitivity to the study drug ligelizumab or its components, or to drugs of similar chemical classes
4. New onset or signs and symptoms of any form of chronic urticarias other than CSU during the preceding studies CQGE031C2302, CQGE031C2303 or CQGE031C2202.
5. Diseases with possible symptoms of urticaria or angioedema
6. Subjects with evidence of helminthic parasitic infection
7. Documented history of anaphylaxis
8. Pregnant or nursing (lactating) women

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-08-2020
Enrollment:	15
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	18-05-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-07-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-03-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-07-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-11-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-01-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	11-03-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-04-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-04-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2019-001792-37-NL
CCMO	NL72720.078.20