A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of LY2951742 in Patients with Chronic Migraine - the REGAIN Study

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Primary To test the hypothesis that at least 1 dose of LY2951742 (120 mg or 240 mg/month) is superior to placebo in the prevention of migraine headache in patients with chronic migraineKey Secondary Objectives If LY2951742 (120 or 240 mg/month) is...

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

Summary

ID

NL-OMON46093

Source
ToetsingOnline

Brief title
REGAIN [15Q-MC-CGAI]

Condition

- Headaches

Synonym
chronic migraine, headache

Research involving
Human

Sponsors and support

Primary sponsor: Eli Lilly

Source(s) of monetary or material Support: Eli Lilly and Company

Intervention

Keyword: CGRP, chronic migraine, headache, LY2951742

Outcome measures

Primary outcome

The overall mean change from baseline in the number of monthly migraine headache days during the 3-month double-blind treatment phase

Secondary outcome

The specific methodology (including testing order, relationship and type I error allocation and propagation) for the tests of the following key secondary endpoints will be specified in the statistical analysis plan:

-The proportion of patients with reduction from baseline >=50% in monthly migraine headache days during the 3-month double-blind treatment phase

-The proportion of patients with reduction from baseline >=75% in monthly migraine headache days during the 3-month double-blind treatment phase

-The proportion of patients with reduction from baseline of 100% in monthly migraine headache days during the 3-month double-blind treatment phase

-Mean change from baseline in the Role Function-Restrictive domain score of the Migraine-Specific Quality of Life Questionnaire version 2.1 (MSQ v2.1) at Month 3

-The overall mean change in the number of monthly migraine headache days requiring medication for the acute treatment of migraine or headache during the 3-month double-blind treatment phase

-The mean change from baseline in the Patient Global Impression of Severity

(PGI-S) score at Month 3

Study description

Background summary

Study 15Q-MC-CGAI (CGAI; REGAIN) will enable a comprehensive clinical assessment of two doses of LY2951742 in a patient population for which the medical need is substantial. This study, along with 2 studies in patients with episodic migraine, is part of a Phase 3 clinical program that is intended to provide pivotal efficacy data to support a registration in patients with migraine.

Study objective

Primary
To test the hypothesis that at least 1 dose of LY2951742 (120 mg or 240 mg/month) is superior to placebo in the prevention of migraine headache in patients with chronic migraine

Key Secondary Objectives
If LY2951742 (120 or 240 mg/month) is statistically significantly superior to placebo on the primary objective, the following key secondary objectives will be tested with adjustment for multiplicity (only the key secondary objectives are listed below):
- To compare LY2951742 with placebo with respect to 50% response rate
- To compare LY2951742 with placebo with respect to 75% response rate
-To compare LY2951742 with placebo with respect to 100% response rate
-To compare LY2951742 with placebo with respect to change in functioning
-To compare LY2951742 with placebo with respect to change in use of acute (abortive) migraine treatment
-To compare LY2951742 with placebo with respect to change in global severity of the migraine condition

Study design

A multisite, randomized, double-blind, parallel, placebo-controlled trial with 5 study periods in patients who meet International Classification of Headache Disorders (ICHD) criteria for a diagnosis of chronic migraine as confirmed during a prospective baseline period.

Intervention

Three treatment arms: LY2951742 (120 mg/month [administered as 1 injection]

with a 240 mg loading dose), LY2951742 (240 mg/month, administered as 2 injections of 120 mg), and placebo. Following a prospective baseline period (30 to 40 days), eligible patients will be randomized in a 2:1:1 ratio to receive placebo, 120 mg/month of LY2951742, or 240 mg/month of LY2951742, respectively, and will begin a 3-month double-blind treatment phase. Patients who complete the double-blind period may enter a 9-month open-label extension phase for treatment with LY2951742. All patients entering the open-label period will receive an initial dose of 240 mg of LY2951742 at the first open-label visit. At the second open-label visit, all patients will receive a 120 mg dose of LY295174; dosing at subsequent visits will be flexible (either 120 mg or 240 mg/month) at the discretion of the investigator. All patients will also be followed for a 4-month, post-treatment phase during which patients will no longer receive any study medication.

Study burden and risks

The study drug is accompanied by certain risks. The most commonly observed adverse events in studies in migraine patients were pain at the site of injection and infection of the upper breathing system, such as bronchitis, cold, or cold-like symptoms. More information about the known and expected benefits, risks, serious adverse events (SAEs) and reasonably anticipated adverse events (AEs) of LY2951742 are to be found in the Investigator*s Brochure (IB). The studyprocedures, including blood draws, also have certain risks. The study drug, the study procedures and the combination may also have other, unknown risks. The risks are described in the subject information sheet. This current study is being carried out in a patient population for which the drug already has shown preliminary evidence of efficacy and safety. In addition, this patient population is experiencing very frequent headaches leading to a high degree of disability, so treatment options are much needed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients are 18 to 65 years of age (inclusive) at the time of screening.;Have a diagnosis of chronic migraine as defined by International Headache Society (IHS) International Classification of Headache Disorders (ICHD)-3 beta.;Migraine onset prior to age 50.

Exclusion criteria

Are currently enrolled in or have participated within the last 30 days or within 5 half-lives (whichever is longer) in a clinical trial involving an investigational product.;Current use or prior exposure to LY2951742 or another CGRP antibody;Are currently receiving medication or other treatments for the prevention of migraine headaches.;Known hypersensitivity to multiple drugs, monoclonal antibodies or other therapeutic proteins, or to LY2951742.;History of persistent daily headache, cluster headache or migraine subtypes including hemiplegic (sporadic or familial) migraine, ophthalmoplegic migraine, and migraine with brainstem aura (basilar-type migraine) defined by IHS ICHD-3 beta.

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:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-02-2016
Enrollment:	32
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Galcanezumeb
Generic name:	LY2951742

Ethics review

Approved WMO Date:	24-11-2015
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	18-01-2016
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	11-04-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	13-07-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Approved WMO Date:	01-08-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	24-11-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	09-02-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	20-03-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	19-06-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	14-08-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	04-09-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	12-12-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	13-12-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO	

Date:	11-02-2019
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	13-02-2019
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	EUCTR2015-001883-21-NL
CCMO	NL55352.075.15

Study results

Date completed:	28-11-2018
Actual enrolment:	54

Summary results
Trial is onging in other countries