A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of LY2951742 in Patients with Episodic Migraine - the EVOLVE-2 Study

Published: 24-11-2015
Last updated: 19-04-2024

PrimaryTo test the hypothesis that at least 1 dose of LY2951742 (120 or 240 mg/month) is superior to placebo in the prevention of migraine headache in patients with episodic migraine.Key Secondary ObjectivesIf LY2951742 (120 or 240 mg/month) is...

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

Summary

ID

NL-OMON45766

Source
ToetsingOnline

Brief title
EVOLVE-2 [I5Q-MC-CGAH]

Condition

- Headaches

Synonym
episodic migraine

Research involving
Human

Sponsors and support

Primary sponsor: Eli Lilly

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

Intervention

Keyword: CGRP, episodic migraine, headache, LY2951742

Outcome measures

Primary outcome

The overall mean change from baseline in the number of monthly migraine headache days during the 6-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 6-month double-blind treatment phase

-The proportion of patients with reduction from baseline >=75% in monthly migraine headache days during the 6-month double-blind treatment phase

-The proportion of patients with a 100% reduction from baseline in monthly migraine headache days during the 6-month double-blind treatment phase

-The 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) (average of Months 4, 5, and 6)

-The overall mean change from baseline in the number of monthly migraine

headache days requiring medication for the acute treatment of

migraine or headache during the 6-month doubleblind treatment phase

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

(PGI-S) score (average of Months 4, 5, and 6)

Study description

Background summary

Study I5Q-MC-CGAH (CGAH; EVOLVE-2) is intended to assess the efficacy and safety of two doses of LY2951742 in the prevention of migraine headache compared with placebo in patients suffering from episodic migraine. Episodic migraine is defined as 4 to 14 migraine headache days (with or without aura) per month.

Study objective

Primary
To test the hypothesis that at least 1 dose of LY2951742 (120 or 240 mg/month) is superior to placebo in the prevention of migraine headache in patients with episodic 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 4 study periods in patients who meet International Classification of Headache Disorders (ICHD) criteria for a diagnosis of migraine as confirmed during a prospective baseline period that demonstrates episodic frequency (4 to 14

migraine headache days per month).

Intervention

Three treatment arms: LY2951742 (120 mg/month with a 240 mg loading dose at the first injection [administered as 2 injections of 120 mg at Visit 3]), LY2951742 (240 mg/month, administered as 2 injections of 120 mg), and placebo. Following a prospective baseline (30-40 days) period, 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 6-month treatment phase. This phase will be followed by 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.

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)
Have a diagnosis of migraine as defined by International Headache Society (IHS) International Classification of Headache Disorders (ICHD)-3 beta guidelines (1.1 or 1.2) (ICHD-3 2013), with a history of migraine headaches of at least 1 year
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
History of migraine subtypes including hemiplegic (sporadic or familial) migraine, ophthalmoplegic migraine, and basilar-type migraine defined by IHS ICHD-3 beta.
History of persistent daily headache, cluster headache or migraine subtypes including hemiplegic (sporadic or familial) migraine, ophthalmoplegic migraine, and migraine with brainstem aura (basilartype 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):	08-02-2016
Enrollment:	48
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Galcanezumab
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:	12-04-2016
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:	13-03-2017
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)

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	EUCTR2015-001882-17-NL
CCMO	NL55350.075.15