A Randomized, Double-Blind, Placebo-Controlled Study of Galcanezumab in Patients 6 to 17 Years of Age with Episodic Migraine - the REBUILD-1

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This study has been transitioned to CTIS with ID 2023-505836-36-00 check the CTIS register for the current data. Main Objective:To demonstrate the superiority of galcanezumab versus placebo in the prevention of migraine in (at least) 1 of the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Headaches
Study type	Interventional

Summary

ID

NL-OMON51686

Source
ToetsingOnline

Brief title
REBUILD-1 I5Q-MC-CGAS

Condition

- Headaches

Synonym
episodic migraine, severe headaches

Research involving
Human

Sponsors and support

Primary sponsor: Eli Lilly

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

Intervention

Keyword: episodic, Galcanezumab, migraine, Pediatric

Outcome measures

Primary outcome

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

Secondary outcome

-Het percentage patiënten met een reductie vanaf baseline van >=50% in maandelijkse migrainehoofdpijndagen tijdens de dubbelblinde behandelingsfase van 3 maanden

-Het percentage patiënten met een afname vanaf baseline van >=75% in maandelijkse migrainehoofdpijndagen tijdens de dubbelblinde behandelingsfase van 3 maanden

- Maandelijks: de eerste maand waarin statistische scheiding in gemiddelde verandering van baseline in het aantal maandelijkse migrainehoofdpijndagen wordt aangetoond en gehandhaafd in alle daaropvolgende maanden tot en met maand 3

- Wekelijks (indien het begon in maand 1): de eerste week waarin statistische scheiding in het aantal migraine-hoofdpijndagen wordt aangetoond en behouden in alle volgende weken (weken 1-4) binnen maand 1

-Dagelijks (indien het begon in week 1): de eerste dag waarop statistische scheiding in het aantal patiënten met migraine-dag wordt aangetoond en gehandhaafd op alle volgende dagen (dag 1-7) in week 1.

-De totale gemiddelde verandering ten opzichte van baseline in het aantal

maandelijkse migraine-hoofdpijndagen met misselijkheid en/of braken tijdens de

dubbelblinde behandelingsfase van 3 maanden

-De totale gemiddelde verandering ten opzichte van baseline in het aantal

maandelijkse migraine-hoofdpijndagen met fotofobie en fonofobie tijdens de

dubbelblinde behandelingsfase van 3 maanden

Study description

Background summary

In this study, galcanezumab is being researched. This study drug is not registered in the Netherlands for episodic migraine in children and adolescents The product is approved for the prevention of migraine in adults. It is known that it is safe and it works for preventing migraine in adults, but it is unknown if the study drug is safe and works for episodic migraine in children and adolescents.

Study objective

This study has been transitioned to CTIS with ID 2023-505836-36-00 check the CTIS register for the current data.

Main Objective:
To demonstrate the superiority of galcanezumab versus placebo in the prevention of migraine in (at least) 1 of the following populations with migraine: the overall pediatric population (6 to 17 year-olds) or the adolescent population (12 to 17 year-olds).

Second Objective:
- To compare galcanezumab with placebo with respect to 50% response rate
- To compare galcanezumab with placebo with respect to 75% response rate
Time to Onset:
* To compare galcanezumab with placebo with respect to:
o the month of onset of effect
o the week of onset of effect within Month 1
o the day of onset of effect within Week 1

-To compare galcanezumab with placebo with respect to change in nausea and/or

vomiting symptoms associated with migraine headache
-To compare galcanezumab with placebo with respect to change in phonophobia and photophobia symptoms associated with migraine headache

Study design

Study CGAS is a multicenter, randomized, double-blind, parallel group, placebo-controlled trial with 5 study periods in patients 6 to 17 years of age who meet International Classification of Headache Disorders (ICHD-3) criteria for a diagnosis of migraine with episodic frequency as confirmed during a 1-month prospective baseline period.

Intervention

Sites will administer subcutaneous injections of galcanezumab or placebo at 3 clinic visits during the double-blind treatment phase and administer galcanezumab at 9 clinic visits during the open-label treatment phase, SP IV (Section 2). The injection may be given in the abdomen, thigh, upper arm or buttocks. Site staff may administer comfort measures (such as topical anesthetic cream, cold compress, or ice pack) to the injection site prior to or after the injection at their clinical discretion or as needed. Use of distraction devices during the injection are also acceptable.
Based on these pediatric dose regimens, the lighter patients (15 to 45 kg) compared with heavier patients (>45 kg) will receive 1 fewer injection and 50% of the total volume at Visit 3, and 50% less volume at Visits 5, 6, and 8 to 15.

See Protocol page 37 and 38, Table 7.1 and Section 7.1.1 for additional details

Study burden and risks

Interim analysis of the ongoing pharmacokinetic (PK) addendum to Study CGAS (n = 25, 21 weighing at least 30 kg and 4 patients weighing less than 30 kg) in which pediatric patients received at least 1 subcutaneous injection with 120 mg galcanezumab (1 mL) indicated no reatment-related SAEs and no discontinuations due to adverse reactions. Most of the AEs of all causality were mild to moderate in severity. All AEs considered to be related to study drug dosing were mild to moderate in severity, and all but one event had resolved. There were no trends of higher AE risk in patients with longer galcanezumab exposure or lower body weight. Vital signs, safety laboratory tests, and electrocardiogram (ECG) findings were not clinically significant.

Given the above safety profile and the need of treatment for children and adolescents with migraine it is supported to evaluate the use galcanezumab in

pediatric population,

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Have a diagnosis of migraine with or without aura as defined by the IHS ICHD-3 guidelines (1.1 or 1.2 according to ICHD-3 [2018]), with a history of migraine headaches of at least 6 months prior to screening.

Exclusion criteria

• Participants who are taking, or are expected to take, therapeutic antibodies during the course of the study (adalimumab, infliximab, trastuzumab, bevacizumab, etc.). Prior use of therapeutic antibodies, other than antibodies to calcitonin gene-related peptide (CGRP) or its receptor, is allowed if that use was more than 12 months prior to baseline.
• Known hypersensitivity to monoclonal antibodies or other therapeutic proteins, or to galcanezumab or its excipients.
• Current use or prior exposure to galcanezumab, another CGRP antibody, or CGRP receptor antibody, including those who have previously completed or withdrawn from this study or any other study investigating a CGRP antibody. Patients must also not have prior oral CGRP antagonist use within 30 days prior to Visit 2.
• History of IHS ICHD-3 diagnosis of new daily persistent headache, cluster headache or migraine subtypes including hemiplegic (sporadic or familial) migraine and migraine with brainstem aura (previously basilar-type migraine).
• History of significant head or neck injury within 6 months prior to screening; or traumatic head injury at any time that is associated with significant change in the quality or frequency of their headaches, including new onset of migraine following traumatic head injury.
• Participants with a known history of intracranial tumors or developmental malformations including Chiari malformations.

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:	Recruiting
Start date (anticipated):	23-09-2022

Enrollment:	2
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Emgality
Generic name:	Galcanezumab LY2951742
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	24-05-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-06-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
EU-CTR	CTIS2023-505836-36-00
EudraCT	EUCTR2017-004351-23-NL
ClinicalTrials.gov	NCT03432286
CCMO	NL80660.056.22