A 12-month prospective, randomized, interventional, global, multi-center, active-controlled study comparing sustained benefit of two treatment paradigms (erenumab qm vs. oral prophylactics) in adult episodic migraine patients

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The purpose of this study is to determine the sustained benefit on safety and efficacy of AMG 334 compared to oral prophylactics in episodic migraine patients who have previously failed 1 to 2 prophylactic migraine treatments and therefore have a...

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

Summary

ID

NL-OMON55516

Source
ToetsingOnline

Brief title
CAMG334A2401 (APPRAISE)

Condition

- Headaches

Synonym
Headache, Migraine

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: AMG334, Episodic, Erenumab, migraine

Outcome measures

Primary outcome

The primary objective is to demonstrate the superiority of subcutaneous

erenumab compared to oral prophylactic(s) on sustained benefit defined as %

subjects completing one-year on the randomized treatment and achieving at least

a 50% reduction from baseline in monthly migraine days at month 12.

Secondary outcome

The secondary objectives are the following:

Objective 1: To evaluate the effect of erenumab compared to oral

prophylactic(s) on overall subject retention defined as % subjects completing

study on randomized treatment

Objective 2: To evaluate the effect of erenumab compared to oral

prophylactic(s) on the change from baseline in monthly migraine days during the

treatment period

Objective 3: To evaluate the effect of erenumab compared to oral

prophylactic(s) on the subject's assessment of the change in clinical status

since the start of treatment as measured by the Patients' Global Impression of

Change (PGIC) Scale

Study description

Background summary

The purpose of this study is to compare the sustained long-term benefit between two treatment paradigms of migraine prophylactic agents (erenumab versus a control arm of oral prophylactics) in episodic migraine patients who have previously failed 1 to 2 prophylactic migraine treatments. Data from this study, in addition to the data generated thus far in the clinical program, will provide important data for clinicians treating migraine patients, particularly for patients who have previously failed existing preventative treatments, as there are limited treatment options. Subsequently it will determine if early use of erenumab during a treatment algorithm is associated with a favorable long-term sustained benefit.

Study objective

The purpose of this study is to determine the sustained benefit on safety and efficacy of AMG 334 compared to oral prophylactics in episodic migraine patients who have previously failed 1 to 2 prophylactic migraine treatments and therefore have a high unmet medical need.

Study design

This study uses a single-cohort, 2-treatment arm (erenumab versus oral SoC prophylactic treatment), parallel-group randomized (2:1 [erenumab (70mg or140mg): SoC oral prophylactic]), open-label design in adult patients with episodic migraine who have previously failed 1 or 2 prophylactic migraine treatments.
The following periods are included in the study design, with study visits at 4-week intervals after completion of screening:
Screening Period (0-2 weeks), Baseline Period (4 weeks) - Open-Label Randomized Treatment Period (52 weeks) * Extension Period (52 weeks)

Intervention

AMG334

Study burden and risks

Possible risks of participation in this study are any side effects of AMG334,

the time investment and extra assesments. See protocol, SmPC and the ABR form section E.

Mogelijke risico's en belasting van deelname aan dit onderzoek zijn bijwerkingen van AMG334, de tijdsinvestering en risico's extra onderzoeksprocedures. Zie ook protocol,SmPC en het ABR formulier sectie E.

Contacts

Public
Novartis

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Novartis

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Adults *18 of age upon entry into screening.
- Documented history of migraine (with or without aura) *12 months prior to screening.
- *4 and <15 days per month of migraine symptoms (based on ICHD-3 criteria)

on average across 3 months prior to screening based on retrospective reporting.
- < 15 days per month of headache symptoms (i.e., migraine and non-migraine)
- Subjects in need for switching by documented failure of 1 or 2 prophylactic therapies in the last 6 months due to either lack of efficacy or poor tolerability. For subjects with 1 prior treatment failure, the failure should have occurred in the last 6 months. For subjects with 2 prior treatment failures, the second treatment failure should have occurred in the last 6 months.

- During baseline period, confirmed migraine frequency of 4 to 14 migraine days and < 15 days of headache symptoms.
- During baseline period, *80% compliance with the headache diary.

Exclusion criteria

- Older than 50 years of age at migraine onset.
- Lack of efficacy or poor tolerability with > 2 treatments from the following 7 medication categories for prophylactic treatment of migraine: 1: Divalproex sodium, sodium valproate, 2: Topiramate, 3: Beta blocker , 4: Tricyclic antidepressants, 5: Serotonin-norepinephrine reuptake inhibitors, 6: Flunarizine, verapamil, 7: Lisinopril, candesartan
- Used a prohibited medication, device, or procedure within 2 months prior to the start of or during baseline or during the treatment period.
- Exposure to botulinum toxin in the head and/or neck region within 4 months prior to the start of the baseline period, during the baseline period, or treatment period.
- Taken the following for any indication in any month during the 2 months prior to the start of the baseline period:
- Ergotamines or triptans on * 10 days per month, or
- Simple analgesics (non-steroidal anti-inflammatory drugs [NSAIDs], acetaminophen) on * 15 days per month, or
- Opioid- or butalbital-containing analgesics on *4 days per month, or
- Device, or procedure that potientially may interfere with the intensity or number of migraine days
- Previous exposure to erenumab or exposure to any other prophylactic CGRP-targeted therapy (prior to and during the study).

Study design

Design

Study phase: 4

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-07-2019
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Aimovig
Generic name:	erenumab
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	07-03-2019
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	17-05-2019
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	01-10-2019
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO	

Date:	04-10-2019
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	06-04-2020
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	21-04-2020
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	30-04-2020
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	13-05-2020
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	02-09-2020
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	14-09-2020
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	21-10-2020
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	02-11-2020
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO	

Date:	10-03-2021
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	24-02-2022
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	EUCTR2018-001228-20-NL
CCMO	NL68689.075.19