A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of AMG 334 in Migraine Prevention

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To evaluate the effect of AMG 334 compared to placebo on the change from baseline in mean monthly migraine days, in subjects with episodic migraine.hypothesis: In subjects with episodic migraine, AMG 334 has a greater reduction from baseline in mean...

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

Summary

ID

NL-OMON43798

Source
ToetsingOnline

Brief title
STRIVE

Condition

- Headaches

Synonym
Headache, Migraine

Research involving
Human

Sponsors and support

Primary sponsor: Amgen

Source(s) of monetary or material Support: Amgen

Intervention

Keyword: AMG334, Migraine, Prevention

Outcome measures

Primary outcome

Change from baseline in mean monthly migraine days. The mean monthly migraine days will be calculated using the monthly migraine days from each of the last three months (months 4, 5, and 6) of the double-blind treatment phase.

Secondary outcome

Secondary Endpoints:

Efficacy:

* Achievement of at least a 50% reduction from baseline in mean monthly migraine days
over the last 3 months (months 4, 5, and 6) of the double-blind treatment phase
* Change from baseline in mean monthly acute migraine-specific medication treatment
days over the last 3 months (months 4, 5, and 6) of the double-blind treatment phase
* Achievement of at least a 5-point reduction from baseline in mean impact on everyday activities domain score over the last 3 months (months 4,5,and 6) of the double-blind treatment phase as measured by the MPFID
* Achievement of at least a 5-point reduction from baseline in mean physical impairment domain score over the last 3 months (months 4,5,and 6) of the double-blind treatment phase as measured by the MPFID

Safety:

* Adverse events

* Clinical laboratory values and vital signs

* Anti-AMG 334 antibodies

Study description

Background summary

Migraine is a profound disabling disorder, aanvalsgewijze hoofdpijnaandoening met een eenjaarsprevalentie van 15-20% in de Nederlandse populatie. Migraine is in the top 10 of the WHO most disabling diseases and belongs to the priority list of under treated, serious disabling brain diseases. Migraine profylaxis is an area with a large "unmedcial need*. Calcitonine Gene Related Peptide (CGRP) receptor antagonisme seems a good candidate to change that. The investigated product AMG334 is an antagonist of the CGRP receptor by which it (besides other effects) could diminish vasodilatation, pain transmission and inflammation in the brain and therefore could reduce migraine attacks.

Study objective

To evaluate the effect of AMG 334 compared to placebo on the change from baseline in mean monthly migraine days, in subjects with episodic migraine.

hypothesis: In subjects with episodic migraine, AMG 334 has a greater reduction from baseline in mean monthly migraine days, compared to placebo. The anticipated treatment effect of AMG 334 compared to placebo is 1.12 and 1.30 monthly migraine days mean reduction from baseline for 70 mg and 140 mg, respectively.

Study design

Phase 3, multicenter, randomized, stratified, double-blind, placebo-controlled, parallel-group study of subjects with episodic migraine. Approximately 852 subjects will be randomized 1:1:1 to placebo, AMG 334 70 mg, or AMG 334 140 mg. NEW: The randomization will be stratified by region (North America vs Other) and treatment status with migraine prophylactic medication (a. current migraine prophylactic medication treatment; b. prior migraine prophylactic medication treatment only; c.no prior migraine prophylactic medication treatment).

Intervention

After signing informed consent, subjects will enter the screening phase. The screening phase is composed of an initial screening phase (up to 3 weeks) followed by a 4-week baseline phase. At the day 1 visit, eligible subjects will be enrolled (ie, randomized) into the 24-week double-blind treatment phase and will begin to receive double-blind investigational product QM SC. At the week 24 visit, subjects in each treatment group will be re-randomized 1:1 to AMG 334 70 mg or AMG 334 140 mg for the 28-week active treatment phase and will begin to receive investigational product QM SC that remains blinded for the dose level only. A safety follow-up visit occurs 16 weeks after the last dose of investigational product. Subjects will use an electronic diary (eDiary) every day throughout the baseline phase, double-blind treatment phase and active treatment phase to report information about their migraine and non-migraine headaches and acute headache medication use. Subjects will have scheduled in-clinic study
visits monthly from week -4 through the end of the active treatment phase.

Study burden and risks

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baseline phase. At the day 1 visit, eligible subjects will be enrolled (ie, randomized) into the
24-week double-blind treatment phase and will begin to receive double-blind investigational
product QM SC. At the week 24 visit, subjects in each treatment group will be re-randomized 1:1
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and active treatment phase to report information about their migraine and non-migraine
headaches and acute headache medication use. Subjects will have scheduled in-clinic study
visits monthly from week -4 through the end of the active treatment phase.
For a full list of study procedures, including the timing of each procedure, please refer to
Section 7 and the Schedule of Assessments (Table 1).

Contacts

Public
Amgen

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Breda 4800 DH
NL
Scientific
Amgen

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NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

age between 18 and 65
history of migraine for at least 12 months
between 4 and 15 migraine days per month in a 3 month period before screening

Exclusion criteria

older than 50 years at migraine onset
history of cluster headache
unable to differentiate migraine form other headaches
no therapeutic response on more than 2 categories of prophylactic treatment
NEW: concomitant use of 2 or more prophylactic treatments. Only one prophylactic

medication may be used throughout study at a stable dose
see page 28 - 30 of the protocol for other criteria.

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):	09-03-2016
Enrollment:	70
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	AMG334
Generic name:	NA

Ethics review

Approved WMO

Date:	30-09-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	23-11-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-12-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-12-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-08-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-08-2016
Application type:	Amendment
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
EudraCT	EUCTR2014-004464-38-NL
ClinicalTrials.gov	NCT02456740
CCMO	NL53715.056.15