A 12-week double-blind, randomized, multicenter study comparing the efficacy and safety of once monthly subcutaneous 140 mg AMG 334 against placebo in adult episodic migraine patients who have failed 2-4 prophylactic treatments (LIBERTY)

Published: 08-11-2016
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The purpose of this study is to determine the safety and efficacy of AMG 334 compared to placebo in episodic migraine patients who havepreviously failed 2 to 4 prophylactic migraine treatments and therefore have a high unmet medical need.

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

Summary

ID

NL-OMON50588

Source
ToetsingOnline

Brief title
CAMG334A2301 (LIBERTY)

Condition

- Headaches

Synonym
Migraine

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma B.V.

Intervention

Keyword: Calcitonin Gene-related Peptide, Episodic migraine, Monoclonal antibody, Treatment failure

Outcome measures

Primary outcome

The primary objective of this study is to evaluate the effect of AMG 334

compared to placebo on the proportion of patients with at least 50%

reduction from baseline in monthly migraine days

Secondary outcome

Objective 1: To evaluate the effect of AMG 334 compared to placebo on the

change from baseline of monthly migraine days in the last month

(Month 3) of the Double-Blind Treatment Epoch

Objective 2: To evaluate the effect of AMG 334 compared to placebo on the

impact on everyday activities sub-domain score as measured by the MPFID on

month 3

Objective 3: To evaluate the effect of AMG 334 compared to placebo on the

physical impairment sub-domain score as measured by the MPFID on month 3

Objective 4: To evaluate the effect of AMG 334 compared to placebo on change

from baseline in monthly acute migraine-specific medication

treatment days in the last month (Month 3) of the Double-Blind Treatment Epoch

Objective 5: To evaluate the effect of AMG 334 compared to placebo on the

proportion of patients with at least 75% reduction from baseline in

monthly migraine days in the last month (Month 3) of the Double-Blind Treatment

Epoch

Objective 6: To evaluate the effect of AMG 334 compared to placebo on the

proportion of patients with a 100% reduction from baseline in

monthly migraine days in the last month (Month 3) of the Double-Blind Treatment

Epoch

Objective 7: To evaluate the safety, tolerability, and immunogenicity of AMG

334 during the entire study

Study description

Background summary

Migraine is one of the most common neurological disorders with a high global prevalence,significant socio-economic burden and substantial impairment and disability of affected patients.Migraineurs are currently being treated for migraine prophylaxis by a variety of drug classes,
many of them being used off-label and often based on insufficient or limited evidence.Based on emerging evidence, Calcitonin Gene-related Peptide (CGRP) is a neuropeptide that prominently contributes to migraine pathophysiology. The CGRP is an attractive target for the development of a migraine-specific prophylactic therapy with the aim of minimizing migraine days and improving patient quality of life in this common and often
disabling disorder. There is a high unmet medical need, in episodic migraine patients who have previously failed 2-4 prophylactic migraine treatments.

Study objective

The purpose of this study is to determine the safety and efficacy of AMG 334 compared to placebo in episodic migraine patients who have
previously failed 2 to 4 prophylactic migraine treatments and therefore have a high unmet medical need.

Study design

This study has a 12-week 2-arm, double-blind, randomized, placebo-controlled, parallel-group design, followed by an optional 156-week open-label epoch

Intervention

AMG334 or placebo

Study burden and risks

When participation part I and II: 46 visits in total , 2 hours per visit, 186 weeks in total.

Physical examination: each visit
ECG: 8x
Subcutaneous injection: 42x (70 ml)
Blood collection: 10x (40-80 ml total)
Women: Pregnancy test: 47x
Completion eDiary: As of first day of treatment till end of study
Completion Questionnaires: 18x

Optional:
1x extra blood collection for pharmacogenetics.

Forbidden co-medication.

Contacts

Public
Novartis

Haaksbergweg 16
Amsterdam 1101 BX
NL
Scientific
Novartis

Haaksbergweg 16
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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

- Documented history of migraine (with or without aura) for * 12 months prior to screening according to the International Classification of Headache Disorders, 3rd Edition (ICHD-3)
- 4 to 14 days per month of migraine symptoms (based on ICHD-3 criteria) on average across the 3 months prior to screening based on retrospective reporting
- <15 days per month of headache symptoms (ie migraine and non-migraine)
- Failed 2 to 4 prior migraine prophylaxis treatments out of the following: Propranolol/metoprolol, topiramate, flunarizine, valproate/divalproex, amitriptyline, venlafaxine, lisinopril, candesartan, locally approved products (e.g. oxeterone or pizotifen)
- Failed one AND failed or not be suitable for a second of the following:
* Propranolol OR metoprolol
* Topiramate
* Flunarizine
- Failed or not be suitable to valproate or divalproex

Exclusion criteria

- Older than 50 years of age at migraine onset
- Unable to differentiate migraine from other headaches
- History of cluster headache or hemiplegic migraine headache
- Failed more than 4 prior migraine prophylaxis treatments [as specified in protocol]
- Use of a prophylactic migraine medication within 5 half-lives, or a device or procedure within one month prior to the start of the baseline phase or during the baseline phase
- Prior Botulinum toxin A treatment in the head/neck region (including cosmetic

use or other licensed indications for Botox ®) within 4 months prior to start of or during the the baseline phase
- Use of the following for any indication in the 1 month prior to the start of the baseline phase or during the baseline phase:
o ergotamines or triptanes *10 days/month, or
o simple analgesics (NSAIDs, acetaminophen, paracetamol) *15 days/month, or
o opioid- or butalbital-containing analgesics *4 days/month

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):	04-04-2017
Enrollment:	30
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	08-11-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	01-02-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	24-02-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	16-03-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	02-05-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	04-05-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	22-11-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	01-12-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	26-04-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	28-05-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	15-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	29-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	04-10-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	13-01-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	19-03-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	10-04-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	28-04-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	27-07-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	05-10-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	15-10-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	04-12-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	03-02-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	EUCTR2016-002211-18-NL
ClinicalTrials.gov	NCT03096834
CCMO	NL58509.058.16