



Study of Efficacy and Safety of AMG 334 in Adult Episodic Migraine Patients

21/11/2024 21:36:30

Main Information

Primary registry identifying number

LBCTR2019060240

Protocol number

AMG334A2302

MOH registration number

49904/2017

Study registered at the country of origin

Yes

Study registered at the country of origin: Specify

Type of registration

Retrospective

Type of registration: Justify

LCTR was recently initiated, original file was previously submitted by Paper

Date of registration in national regulatory agency

20/12/2017

Primary sponsor

Novartis Pharma Services Inc.

Primary sponsor: Country of origin

Novartis Pharmaceuticals

Date of registration in primary registry

17/12/2019

Date of registration in national regulatory agency

20/12/2017

Public title

Study of Efficacy and Safety of AMG 334 in Adult Episodic Migraine Patients

Acronym

EMPOWER

Scientific title

A 12-week Double-blind, Randomized, Multi-center Study Comparing the Efficacy and Safety of Once Monthly Subcutaneous AMG 334 Against Placebo in Adult Episodic Migraine Patients (EMPOWER)

Acronym

Brief summary of the study: English

The purpose of this study is to evaluate the efficacy and safety of AMG334 in countries beyond the United States (US) and European Union (EU).

Brief summary of the study: Arabic

أسبوعًا تقارن ما بين فعالية وسلامة جرعة شهرية واحدة تحت الجلد من دواء 12دراسة متعددة المراكز، عشوائية التوزيع، مزدوجة التعمية من AMG 334 (EMPOWER) مقابل الدواء الوهمي لدى مرضى بالغين مصابين بالصداع النصفي العرضي

Health conditions/problem studied: Specify

Migraine

Interventions: Specify

•Biological: Erenumab

AMG334 is a fully human monoclonal antibody targeting the CGRP receptor under development for migraine prophylaxis in adults.

•Other: Placebo

Placebo will match the active study drug and will be administered similarly.

Key inclusion and exclusion criteria: Inclusion criteria

- 1.Documented history of migraine in the 12 months prior to screening
- 2.4-14 days per month of migraine symptoms



3.>=80% diary compliance during the Baseline period

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Exclusion criteria

- 1.>50 years old at migraine onset
- 2.Pregnant or nursing
- 3.History of cluster or hemiplegic headache
- 4.Evidence of seizure or major psychiatric disorder
- 5.Score of 19 or higher on the BDI
- 6.Active chronic pain syndrome
- 7.Cardiac or hepatic disease

Type of study

Interventional

Type of intervention

Pharmaceutical

Trial scope

Other

Study design: Allocation

Randomized controlled trial

Study design: Control

Placebo

Study design: Purpose

Treatment

Study design: Assignment

Parallel

IMP has market authorization

Yes, Worldwide

Name of IMP

erenumab (AIMOVIG)

Type of IMP

Others

Pharmaceutical class

Erenumab (Aimovig) is a human monoclonal immunoglobulin G2 (IgG2) that is directed against the canonical CGRP receptor, where it inhibits and blocks the action of CGRP.

Therapeutic indication

Preventive treatment of migraine in adults.

Therapeutic benefit

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age maximum

65

Type of intervention: Specify type

N/A

Trial scope: Specify scope

Study design: Masking

Blinded (masking used)

Study phase

3

Study design: Specify purpose

N/A

Study design: Specify assignment

N/A

IMP has market authorization: Specify

USA, Europe (Austria, Croatia, Czech republic, Denmark, Estonia, Finland, Germany, Iceland, Italy, Latvia, Poland, Portugal, Norway, Sweden, Switzerland, UK)

Year of authorization

Month of authorization



The primary efficacy endpoint was 50% reduction in MMD while change from baseline in MMD was a secondary endpoint, also showed positive outcomes. Considering the totality of data, erenumab 70 mg has shown robust and consistent clinically and statistically significant efficacy with no significant dose-dependent adverse events, while erenumab 140 mg has shown even greater treatment effects along with a favorable safety and tolerability profile that was similar to erenumab 70 mg.

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration**Target follow-up duration: Unit****Number of groups/cohorts****Biospecimen retention**

Samples with DNA**

Biospecimen description

A central laboratory will be used for analysis of all specimens collected.
Quintiles Ltd. – Scotland; Q² Solutions; The Alba Campus; Rosebank; Livingston; West Lothian; EH54 7EG; United Kingdom; Telephone: 01506816043
Hematology: red blood cells (RBCs), nucleated RBCs, hemoglobin, hematocrit, MCV, MCH, MCHC, RDW, reticulocytes, platelets, white blood cells (WBCs), WBC differential. The differential will measure: bands/stabs, neutrophils, eosinophils, basophils, lymphocytes, monocytes, myeloblasts, promyelocytes, myelocytes, metamyelocytes, and atypical lymphocytes.
Chemistry: sodium, potassium, chloride, bicarbonate, total protein, albumin, calcium, magnesium, phosphorus, glucose, BUN/urea, bilirubin (direct and total), alkaline phosphatase, ALT (SGPT), AST (SGOT), total cholesterol, HDL, LDL, triglycerides, CPK, and eGFR.
Urinalysis: specific gravity, pH, blood, protein, glucose, bilirubin, WBC, RBC, epithelial cells, bacteria, casts, and crystals

Target sample size

49

Actual enrollment target size

49

Date of first enrollment: Type

Actual

Date of first enrollment: Date

08/02/2018

Date of study closure: Type

Actual

Date of study closure: Date

07/02/2020

Recruitment status

Complete

Recruitment status: Specify**Date of completion**

31/05/2019

**IPD sharing statement plan**

Yes

IPD sharing statement description

Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

This trial data availability is according to the criteria and process described on www.clinicalstudydatarequest.com

Additional data URL

<https://clinicaltrials.gov/ct2/show/record/NCT03333109>

Admin comments**Trial status**

Approved

Secondary Identifying Numbers

| Full name of issuing authority | Secondary identifying number |
|--------------------------------|------------------------------|
| Clinicaltrials.gov | NCT03333109 |

Sources of Monetary or Material Support

| Name |
|-------------------------------|
| Novartis Pharma Services Inc. |

Secondary Sponsors

| Name |
|------|
| NA |



Contact for Public/Scientific Queries

| Contact type | Contact full name | Address | Country | Telephone | Email | Affiliation |
|--------------|-------------------|------------|---------|------------------------|-------------------------------|---|
| Public | Taghrid Hajj | Beirut | Lebanon | 03/494008 | taghridelhajj@gmail.com | Rafik Hariri University Hospital |
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| Public | Naji Riachi | Beirut | Lebanon | 03/229324 | naji.riachi@laumcrh.com | Lebanese American University Medical Center Rizk Hospital |
| Public | Aline Mourad | Beirut | Lebanon | 70/472332 | aline_mourad@hotmail.com | Saint Georges Hospital University Medical Center |

Centers/Hospitals Involved in the Study

| Center/Hospital name | Name of principles investigator | Principles investigator speciality | Ethical approval |
|---|---------------------------------|------------------------------------|------------------|
| Rafic Hariri University Hospital | Dr. Taghrid Hajj | Neurologist | Approved |
| American University of Beirut Medical Center | Dr. Achraf Makki | Neurologist | Approved |
| Bellevue Medical Center | Dr. Ghassan Mehanna | Neurologist | Approved |
| Ain Wazein Medical Village | Dr. Shawkat Beayni | Neurologist | Approved |
| Makassed General Hospital | Dr. Salim Atrouni | Neurologist | Approved |
| Lebanese American University Medical Center Rizk Hospital | Dr. Naji Riachi | Neurologist | Approved |
| Saint George Hospital University Medical Center | Dr Aline Mourad | Neurologist | Approved |



| Ethics Review | | | | |
|---|---------------|--------------------|---------------------------------------|-----------------------------|
| Ethics approval obtained | Approval date | Contact name | Contact email | Contact phone |
| American University of Beirut Medical Center | 14/06/2018 | Fouad Ziyadeh | fz05@aub.edu.lb | +961 (0) 1 350 000 ext:5445 |
| Saint George Hospital University Medical Center | 21/06/2018 | Michel Daher | mndaaher@stgeorgehospital.org | +961 (0)1 441 733 |
| Bellevue Medical Center | 25/10/2017 | Ghassan Maalouf | gmaalouf@bmc.com.lb | +961 (0) 1 682666 ext 7600 |
| Ain w Zein Medical Village | 23/12/2017 | Khaled Abdel Baki | Khaled.abdelbaki@awmedicalvillage.org | +961 (0) 5 509 001 ext 2000 |
| Makassed General Hospital | 09/11/2017 | Mariam Rajab | research.makassed@hotmail.com | 01636941 |
| Lebanese American University- University Medical Center Rizk Hospital | 24/01/2018 | Christine Chalhoub | christine.chalhoub@lau.edu.lb | +961 9 547254 ext. 2340 |
| Rafic Hariri University Hospital | 29/11/2017 | Rawan Yamout | rawan.yamout@crurhuh.com | 018300000 ext 2036 |

| Countries of Recruitment |
|--------------------------|
| Name |
| Lebanon |
| Argentina |
| India |
| Republic of Korea |
| Malaysia |
| Mexico |
| Philippines |
| Singapore |
| Taiwan |
| Thailand |
| Viet Nam |



Health Conditions or Problems Studied

| Condition | Code | Keyword |
|-----------|----------------|----------|
| Migraine | Migraine (G43) | Migraine |

Interventions

| Intervention | Description | Keyword |
|-------------------------------------|-------------------------------------|-------------------------------------|
| ICF, Physical Exam, ECG, local Labs | ICF, Physical Exam, ECG, local Labs | ICF, Physical Exam, ECG, local Labs |

Primary Outcomes

| Name | Time Points | Measure |
|---|-------------|----------|
| Change from baseline in monthly migraine days at the last month | 3 months | 3 months |

Key Secondary Outcomes

| Name | Time Points | Measure |
|---|-------------|----------|
| •Achievement of at least a 50% reduction from baseline in monthly migraine days | 3 months | 3 months |
| •Change from Baseline in acute migraine-specific medication treatment days | 3 months | 3 months |
| •Change from Baseline in headache impact scores as measured by the HIT-6 | 3 months | 3 months |



Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files