



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

04/04/2025 14:55:46

## 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**

15/12/2020

**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; Q<sup>2</sup> 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**

13/11/2020

**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](http://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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## 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	mndaher@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**