



Phase III Study of Efficacy and Safety of Secukinumab Versus Placebo, in Combination With Glucocorticoid Taper Regimen, in Patients With Polymyalgia Rheumatica (PMR)

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Main Information

Primary registry identifying number

LBCTR2023035313

Protocol number

CAIN457C22301

MOH registration number

Study registered at the country of origin

Yes

Study registered at the country of origin: Specify

Type of registration

Prospective

Type of registration: Justify

N/A

Date of registration in national regulatory agency

Primary sponsor

Novartis Pharma AG

Primary sponsor: Country of origin

Novartis Pharma AG

Date of registration in primary registry

26/03/2024

Date of registration in national regulatory agency

Public title

Phase III Study of Efficacy and Safety of Secukinumab Versus Placebo, in Combination With Glucocorticoid Taper Regimen, in Patients With Polymyalgia Rheumatica (PMR)

Acronym

Scientific title

A Randomized, Parallel-group, Double-blind, Placebo-controlled, Multicenter Phase III Trial to Evaluate Efficacy and Safety of Secukinumab Administered Subcutaneously Versus Placebo, in Combination With a Glucocorticoid Taper Regimen, in Patients With Polymyalgia Rheumatica (PMR)

Acronym

Brief summary of the study: English

The purpose of this study is to demonstrate the efficacy and safety of secukinumab 300 milligram (mg) and 150 mg administered subcutaneously (s.c.) for 52 weeks in combination with prednisone tapered over 24 weeks in adult participants with PMR who have recently relapsed

Brief summary of the study: Arabic

تجربة عشوائية التوزيع ومتوازية المجموعات ومزدوجة التعمية ومرتكزة على المقارنة بدواء وهمي وتمتددة المراكز في المرحلة الثالثة، لتقييم فعالية وسلامة دواء سيكوكينوماب المعطى تحت الجلد مقابل الدواء الوهمي، بالاشتراك مع نظام تقليل تدريجي للهرمونات القشرية السكرية، لدى مرضى مصابين بألم العضلات الروماتيزمي

Health conditions/problem studied: Specify

Polymyalgia Rheumatica

Interventions: Specify

Drug: Secukinumab 300 mg

Taken subcutaneously every 4 weeks until Week 48 in combination with a 24-week prednisone taper regimen





Other Name: AIN457
Drug: Secukinumab 150 mg
Taken subcutaneously every 4 weeks until Week 48 in combination with a 24-week prednisone taper regimen
Other Name: AIN457
Other: Placebo to secukinumab
Taken subcutaneously every 4 weeks until Week 48 in combination with a 24-week prednisone taper regimen

Key inclusion and exclusion criteria: Inclusion criteria

Inclusion Criteria:

- 1- Signed informed consent must be obtained prior to participation in the study
- 2- Male or non-pregnant, non-lactating female participants at least 50 years of age.
- 3- Diagnosis of PMR according to the provisional American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) classification criteria: Participants ≥ 50 years of age with a history of bilateral shoulder pain accompanied by elevated C-reactive protein (CRP) concentration (≥ 10 mg/L) and/or elevated erythrocyte sedimentation rate (ESR) (≥ 30 mm/hr) who scored at least 4 points from the following optional classification criteria:

Morning stiffness > 45 minutes (min) (2 points)

Hip pain or restricted range of motion (1 point)

Absence of rheumatoid factor and/or anti-citrullinated protein antibodies (2 points)

Absence of other joint involvement (1 point)

4- Participants must have a history of being treated for at least 8 consecutive weeks with prednisone (≥ 10 mg/day or equivalent) at any time prior to screening

5- Participants must have had at least one episode of PMR relapse while attempting to taper prednisone at a dose that is ≥ 5 mg/day (or equivalent) within the past 12 weeks prior to BSL. Diagnosis of a PMR relapse is defined as participant meeting both of the following:

Recurrence of bilateral shoulder girdle and/or bilateral hip girdle pain associated with inflammatory stiffness with or without additional symptoms indicative of PMR relapse (such as constitutional symptoms) within 12 weeks prior to BSL that are in the opinion of the Investigator not due to other diseases that may mimic PMR such as osteoarthritis in shoulders or hips, polyarticular calcium pyrophosphate deposition disease, rotator cuff disease, adhesive capsulitis (frozen shoulder) or fibromyalgia.

Elevated ESR (≥ 30 mm/hr) and/or elevated CRP ($>$ upper limit of normal (ULN)) attributable to PMR at the time of relapse and/or at screening

6- Participants must have been treated as per local treatment recommendations following the latest PMR relapse and must be on prednisone of at least 7.5 mg/day (or equivalent) and not exceeding 25 mg/day at screening and during the screening period

Other protocol-defined inclusion/exclusion criteria may apply

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

50

Key inclusion and exclusion criteria: Age maximum

99

Key inclusion and exclusion criteria: Exclusion criteria

Exclusion Criteria:

- 1- Evidence of GCA as indicated by typical (cranial) symptoms (e.g., persistent or recurrent localized headache, temporal artery or scalp tenderness, jaw claudication, blurry or loss of vision, symptoms of stroke), extremity claudication, imaging and/or temporal artery biopsy result
- 2- Concurrent rheumatoid arthritis or other inflammatory arthritis or other connective tissue diseases, such as but not limited to systemic lupus erythematosus, systemic sclerosis, vasculitis, myositis, mixed connective tissue disease, and ankylosing spondylitis
- 3- Concurrent diagnosis or history of neuropathic muscular diseases
Inadequately treated hypothyroidism (e.g., persistence of symptoms, lack of normalization of serum TSH despite regular hormonal replacement treatment)
- 4- Previous exposure to secukinumab or other biologic drug directly targeting IL-17 or IL-17 receptor
- 5- Participants treated with tocilizumab or other IL-6/IL6-receptor inhibitors within 12 weeks or within 5 half-lives (whichever is longer) prior to BSL; participant who did not respond to or experienced a relapse during treatment are excluded from enrollment into the study

Other protocol-defined inclusion/exclusion criteria may apply

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

Study design: Masking



Randomized controlled trial

Study design: Control

Placebo

Study design: Purpose

Treatment

Study design: Assignment

Parallel

IMP has market authorization

Yes, Lebanon and Worldwide

Name of IMP

Secukinumab

Type of IMP

Immunological

Pharmaceutical class

Interleukin 17A inhibitor (IL-17i)

Therapeutic indication

Polymyalgia Rheumatica (PMR)

Therapeutic benefit

Treatment

Study model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Number of groups/cohorts

Biospecimen retention

Samples with DNA**

Blinded (masking used)

Study phase

3

Study design: Specify purpose

N/A

Study design: Specify assignment

N/A

IMP has market authorization: Specify

Switzerland, UK, France, Italy, Portugal, Belgium, Spain, Canada, United States, Australia,,Jordan, KSA, Oman, Kuwait, UAE, Qatar, Bahrain

Year of authorization

2016

Month of authorization

3

Study model: Explain model

N/A

Time perspective: Explain time perspective

N/A

Target follow-up duration: Unit

Biospecimen description



shipped to Q2 central lab

Target sample size

8

Actual enrollment target size**Date of first enrollment: Type**

Anticipated

Date of first enrollment: Date

04/12/2023

Date of study closure: Type

Anticipated

Date of study closure: Date

22/12/2025

Recruitment status

Pending

Recruitment status: Specify**Date of completion****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/NCT05767034?term=CAIN457C22301&draw=2&rank=1>

Admin comments**Trial status**

Approved

Secondary Identifying Numbers

| Full name of issuing authority | Secondary identifying number |
|--------------------------------|------------------------------|
| Clinicaltrials.gov | NCT05767034 |

Sources of Monetary or Material Support

| Name |
|--------------------|
| Novartis Pharma AG |



Secondary Sponsors

Name

NA

Contact for Public/Scientific Queries

| Contact type | Contact full name | Address | Country | Telephone | Email | Affiliation |
|--------------|-------------------|--|---------|-------------------------|-------------------------------|---|
| Public | Nelly Ziade | Hotel Dieu de France Hospital, Asrafieh, Lebanon | Lebanon | 0096170973214 | nelly.zoghbi@usj.edu.lb | Hotel Dieu de France Hospital |
| Scientific | Hind Khairallah | Sin El Fil | Lebanon | 009611512002 Ext. 271 E | hind.khairallah@fattal.com.lb | Khalil Fattal et Fils s.a.l |
| Public | Kamel Mroue | Hammoud Hospital University Medical Center, Saïda, Lebanon | Lebanon | 009613844769 | khmroue@gmail.com | Hammoud Hospital University Medical Center |
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| Public | Imad Uthman | American University of Beirut | Lebanon | 009613379098 | iuthman@aub.edu.lb | American University of Beirut |

Centers/Hospitals Involved in the Study

| Center/Hospital name | Name of principles investigator | Principles investigator speciality | Ethical approval |
|---|---------------------------------|------------------------------------|------------------|
| Hotel Dieu de France Hospital | Nelly Ziade | Rheumatology | Approved |
| Hammoud Hospital University Medical Center | Kamel Mroue | Rheumatology | Approved |
| Saint George Hospital University Medical Center | Lama Azar | Rheumatology | Approved |
| American University of Beirut | Imad Uthman | Rheumatology | Approved |



Ethics Review

| Ethics approval obtained | Approval date | Contact name | Contact email | Contact phone |
|---|---------------|---------------|-------------------------------|----------------------------------|
| Hotel Dieu de France | 07/02/2023 | Sami Richa | cue@usj.edu.lb | 00961421229 |
| Hammoud Hospital University Medical Center | 12/12/2022 | Ibrahim Omeis | iomeis@hammoudhospital.org | +961 (0) 7 723111 ext 1222/ 1223 |
| Saint George Hospital University Medical Center | 11/08/2023 | Michel Daher | mndaheer@stgeorgehospital.org | 009611441733 |
| Saint George Hospital University Medical Center | 18/09/2023 | Rami Mahfouz | rm11@aub.edu.lb | 009611350000 ext 5445 |

Countries of Recruitment

| Name |
|--------------------------|
| United States of America |
| Switzerland |
| Argentina |
| Australia |
| Canada |
| Japan |

Health Conditions or Problems Studied

| Condition | Code | Keyword |
|------------------------|--------------------------------|------------------------|
| Polymyalgia rheumatica | Polymyalgia rheumatica (M35.3) | Polymyalgia rheumatica |

Interventions

| Intervention | Description | Keyword |
|---|---|---|
| Consenting, IMP administration, Laboratory testing, imaging | Consenting, IMP administration, Laboratory testing, imaging | Consenting, IMP administration, Laboratory testing, imaging |



Primary Outcomes

| Name | Time Points | Measure |
|---|----------------------|--|
| Proportion of patients achieving complete sustained remission | Time Frame: 52 Weeks | Sustained remission at Week 52 is defined as a participant meeting all of the following: • achieved remission at Week 12 AND all of the following, sustained from Week 12 to Week 52: no recurrence of signs or symptoms, attributable to PMR, that requires escape treatment or rescue treatment no new diagnosis of Giant cell arteritis (GCA), that requires escape treatment or rescue treatment Remission at Week 12 is defined as a participant meeting all of the following at Week 12: no use of escape treatment or rescue treatment prior to Week 12 no signs or symptoms attributable to PMR, that requires escape treatment or use of rescue treatment, at Week 12 no new diagnosis of GCA, that requires escape treatment or rescue treatment, at Week 12 |

Key Secondary Outcomes

| Name | Time Points | Measure |
|---|----------------------|---|
| Proportion of patients achieving complete sustained remission | Time Frame: 52 Weeks | Complete sustained remission at Week 52 is defined as participant meeting all of the following: achieved sustained remission no clinically relevant elevation of Erythrocyte sedimentation Rate (ESR) and/or C-reactive protein (CRP) at ≥ 2 consecutive scheduled visits from Week 12 to Week 52 |
| Adjusted annual cumulative glucocorticoid (GC) dose adjusted by duration of study follow-up | Time Frame: 52 Weeks | Adjusted annual cumulative GC dose is cumulative GC dose through Week 52 adjusted by duration of study follow-up |
| Time to first use of escape treatment or rescue treatment as measured in days | Time Frame: 52 Weeks | First use of escape treatment or rescue treatment is defined as the first time when the escape treatment or rescue treatment is used |
| Change in FACIT-Fatigue Score | Time Frame: 52 Weeks | The Functional Assessment of Chronic Illness Therapy - Fatigue (FACIT-Fatigue) is a 13-item questionnaire that assesses self-reported fatigue and its impact upon daily activities and function. The purpose of collecting available FACIT-Fatigue data is to assess the impact of fatigue on participants with PMR |
| Change in HAQ-DI score | Time Frame: 52 Weeks | The Health Assessment Questionnaire - Disability Index (HAQ-DI) is used to assess the long-term influence of chronic disease on a participant's level of functional ability and activity restriction. The purpose of the HAQ-DI is to assess the functional ability of subjects with PMR |



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