A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Safety and Efficacy of ABBV-154 in Subjects with Polymyalgia Rheumatica (PMR) Dependent on Glucocorticoid Treatment

Published: 23-08-2021
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To assess the safety and efficacy of ABBV-154 versus placebo in subjects with PMR, who are dependent on treatment with glucocorticoids withdoses of at least 5 mg/day prednisone equivalent (glucocorticoindependent PMR).

Ethical review	Approved WMO
Status	Completed
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON54200

Source
ToetsingOnline

Brief title
M20-370

Condition

- Autoimmune disorders

Synonym
PMR, polymyalgia rheumatica

Research involving

Human

Sponsors and support

Primary sponsor: AbbVie Deutschland GmbH & Co. KG
Source(s) of monetary or material Support: AbbVie

Intervention

Keyword: anti-TNF, Glucocorticoids, Polymyalgia Rheumatica

Outcome measures

Primary outcome

Time to flare, where flare is defined as follows:

• Presence of clinical signs and symptoms of PMR

AND

• Requirement to increase the glucocorticoid dose per investigator.

Clinical signs and symptoms of PMR are defined as shoulder and/or hip girdle pain with inflammatory stiffness, neck pain with inflammatory stiffness, or new or worsened limited range of motion of hips and/or shoulders that are not due to other causes

Timepoint of evaluation: week 24

Secondary outcome

• Achievement of flare-free state up to Week 24

• Cumulative glucocorticoid dose by 24 weeks

• Change from Baseline in glucocorticoid dose at Week 24

Study description

Background summary

Polymyalgia rheumatica (PMR) is an inflammatory disease causing shoulder, hip, and neck pain and stiffness, in adults aged 50 years or older. This study evaluates how safe and effective ABBV-154 is in participants with glucocorticoid-dependent PMR. Adverse events and change in disease activity will be assessed.

Study objective

To assess the safety and efficacy of ABBV-154 versus placebo in subjects with PMR, who are dependent on treatment with glucocorticoids with doses of at least 5 mg/day prednisone equivalent (glucocorticoindependent PMR).

Study design

Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging

Intervention

The study is compromised of a 52 week double-blind, placebo-controlled period and a follow-up visit 70 days after the last dose of the study drug. All participants will receive a glucocorticoid taper along with the assigned dose of ABBV-154 or placebo, subcutaneously (SC) every other week (eow).

Study burden and risks

There may be higher treatment burden for participants in this trial compared to their standard of care. Participants will attend regular visits during the study at a hospital or clinic. The effect of the treatment will be checked by medical assessments, blood tests, checking for side effects and completing questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Adults at least 50 years of age with a clinical diagnosis of PMR and fulfillment of the 2012 EULAR/ACR provisional classification criteria for PMR.
2. Following a confirmed diagnosis of PMR, subject must have shown a clinical response to prednisone (or equivalent).
3. Subject must have had at least 2 episodes of unequivocal PMR flare while attempting to taper prednisone, with the dose of prednisone (or equivalent) at the time of flare >= 5 mg/day, prior to Baseline; the most recent flare must have been within 24 weeks of Baseline. Unequivocal PMR flare is defined as clinical signs and symptoms of PMR (shoulder and/or hip girdle pain with inflammatory stiffness, neck pain with inflammatory stiffness, or new or worsened limited range of motion of hips and/or shoulders) that resulted in an increase in glucocorticoid dose.
4. Subject must be on a stable prednisone (or equivalent) dose of 5 to 15 mg/day for >= 2 weeks prior to Baseline. Subjects may be on up to 25 mg/day at the Screening Visit provided that the subject is able to taper to 15 mg/day or less, with a stable dose >= 2 weeks prior to Baseline.
5. Subject must be willing to follow the protocol-defined glucocorticoid tapering regimen.

Exclusion criteria

1. Subject must have discontinued use of immunomodulators other than prednisone (or equivalent) and hydroxychloroquine prior to Baseline.
2. Subjects requiring > 25 mg/day of prednisone to control confirmed PMR are excluded
3. Subject must not exhibit clinical signs and symptoms of PMR (shoulder and/or hip girdle pain with inflammatory stiffness, neck pain with inflammatory stiffness, or new or worsened limited range of motion of hips and/or shoulders) within 2 weeks of Baseline

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-10-2021
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ABBV-154
Generic name:	ABBV-154
Product type:	Medicine

Brand name:	Prednisolone
Generic name:	Prednisolone
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	23-08-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	10-11-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-03-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	26-03-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	11-04-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	02-06-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	30-06-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	13-07-2022

Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	03-08-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	12-01-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	29-01-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-02-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	20-03-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	EUCTR2020-00533-39-NL
ClinicalTrials.gov	NCT04972968
CCMO	NL77653.028.21

Study results

Date completed: 27-04-2023

Results posted: 06-08-2024

Actual enrolment: 3

First publication
18-07-2024