A randomized, double-blind, placebo-controlled multicenter phase 2 dose-ranging study to assess the safety and efficacy of multiple ianalumab doses administered subcutaneously in patients with moderate to severe primary Sjögren*s Syndrome

Published: 19-04-2017
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To determine the dose-response relationship of VAY736 for key efficacy and safety parameters.

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

Summary

ID

NL-OMON50297

Source
ToetsingOnline

Brief title
CVAY736A2201

Condition

- Autoimmune disorders

Synonym
Sjögren□s Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma B.V. (sponsor/verrichter van dit onderzoek)

Intervention

Keyword: fase 2, placebo, Sjogren's disease, VAY736

Outcome measures

Primary outcome

To demonstrate a dose response of VAY736 defined as change in ESSDAI from

baseline at 24 weeks

Secondary outcome

To assess a dose response of VAY736 in the change from baseline of ESSPRI at 24

weeks

To assess a dose response of VAY736 in the change from baseline of the

Functional Assessment of Chronic Illness Therapy-Fatigue Scale (FACIT-F) at 24

weeks

To assess changes from baseline in PhGA of the patient*s overall disease

activity at week 24

To assess a dose response of VAY736 in the change from baseline of SF-36 at 24

weeks

To evaluate the effects of VAY736 on salivary gland function at 24 weeks

To evaluate CD19+ B-cell counts before and after VAY736 treatment, and time to

recovery

To assess safety and tolerability of VAY736 through incidence of AEs, SAEs, and

monthly safety laboratory tests

To assess immunogenicity (IG) of VAY736 by measuring serum anti-VAY736

antibodies

To assess PK of VAY736 after multiple s.c. doses at multiple time points

Study description

Background summary

Primary Sjögren*s Syndrome (pSS) is a chronic autoimmune disease of unknown etiology, characterized by lymphoid infiltration and progressive destruction of exocrine glands. Current standard-of-care (SoC) treatment for pSS patients is limited to symptomatic care for the mucosal signs and symptoms (dryness). Steroids and conventional disease modifying antirheumatic drugs (DMARDs), although used in selected patients, have not been proven efficacious, and no pharmacologic intervention is effective against the severe, disabling fatigue. Hence, there are no approved treatments available for moderate to severe (i.e., systemic) pSS.
The 12-week efficacy results in pSS clinical outcomes observed in the proof of concept study VAY736X2201 with single infusions of two different i.v. doses of VAY736 (3 mg/kg and 10 mg/kg) in 27 patients suggest early and clinically meaningful improvements in signs and symptoms compared to placebo. All patients will be treated with VAY736 in one of the treatment arms.

Study objective

To determine the dose-response relationship of VAY736 for key efficacy and safety parameters.

Study design

This is a randomized, double-blind, placebo-controlled, multicenter, parallel-group trial in patients with active pSS. The study treatment period will last for 24 weeks and for a subset of patients up to 52 weeks. A post treatment safety follow up period for all patients will last for a minimum of 20 weeks.

Intervention

VAY736 or placebo

Study burden and risks

When participating in part 1, 2 and 3: Minimum of 18 visits, duration vary from 1-4 hours per visit, total study time minimal 72 weeks.
- Physical examination also Sjogren specifically: every visit
- Biopsy of the saliva: optional if participating in substudy
- Saliva production: 6 x
- Tear fluid production: 6x
- ECG: 5x
- Subcutaneous injections: starting from randomization every 4 weeks two injections (150 ml each injection)
- At first injection intravenous Methylprednisolone administration.
- Blood collection: every visit
- Filling out questionnaires: every visit

Optional:
- 1 x extra blood collection for farmacogenetisch research

Patients who do not have part 3 have fewer visits.
There is forbidden co-medication.

Contacts

Public
Novartis

Haaksbergweg 16
Amsterdam 1101 BX
NL

Scientific
Novartis

Haaksbergweg 16
Amsterdam 1101 BX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Fulfilled revised European US consensus criteria for pSS
- Seropositive at screening for anti-Ro/SSA antibodies
- See protocol for other protocol-defined inclusion criteria

Exclusion criteria

- Secondary Sjogren*s syndrome
- Use of other investigational drugs
- Active viral, bacterial or other infections
- Positive hepatitis B, hepatitis C, HIV or tuberculosis test results at screening
- See protocol for other protocol-defined exclusion criteria

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: Recruiting

Start date (anticipated):	26-03-2018
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ianalumab
Generic name:	ianalumab

Ethics review

Approved WMO Date:	19-04-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-07-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-07-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-08-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-10-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	

Date:	17-10-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-04-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-05-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-06-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-07-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-09-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-10-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-12-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	13-12-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-07-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-08-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-10-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-05-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-07-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-08-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2016-003292-22-NL
ClinicalTrials.gov	NCT02962895
CCMO	NL60083.078.17