A Phase 2, Multicenter, Randomized, Double blind, Parallel group, Placebo controlled Study Evaluating the Safety and Efficacy of Treatment with Ustekinumab or Golimumab in Subjects with Chronic Sarcoidosis

Published: 29-07-2009
Last updated: 06-05-2024

See above

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON36553

Source
ToetsingOnline

Brief title
1275148SCD2001

Condition

- Other condition
- Lower respiratory tract disorders (excl obstruction and infection)
- Skin and subcutaneous tissue disorders NEC

Synonym
sarcoïdose

Health condition

Sarcoïdose is een systeemziekte, gekenmerkt door granulomen.

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag
Source(s) of monetary or material Support: Centocor Inc.

Intervention

Keyword: Chronic sarcoidosis, CNTO 1275 / Ustekinumab, CNTO 148 / Golimumab, Safety and efficacy

Outcome measures

Primary outcome

See above

Secondary outcome

See above

Study description

Background summary

See above

Study objective

See above

Study design

See above

Intervention

See above

Study burden and risks

See above

Contacts

Public
Janssen-Cilag

dr. Paul Janssenweg 150
5026 RH Tilburg
NL
Scientific
Janssen-Cilag

dr. Paul Janssenweg 150
5026 RH Tilburg
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Male or female >=18 to <= 85 years of age
2. Have histologically proven sarcoidosis with an onset date of >= 2 years prior to screening with at least 1 of the following:
a. pulmonary sarcoidosis defined as requiring:
1) A diagnosis of sarcoidosis with evidence of lung parenchymal disease (Stage II, III or IV on chest radiograph). For subjects with Stage IV sarcoidosis, the chest radiograph should be

interpreted as having interstitial infiltrates without cavitating disease, AND
2) a FVC of >=45% and <= 80% of the predicted normal value at screening, AND
3) an MRC dyspnea score of > 2 at screening, AND
4) a 6 minute walk distance between 100 to 550 meters at screening, AND
5) <= 15% absolute change in percent-predicted FVC at the baseline visit relative to the screening visit
AND/OR
b. skin sarcoidosis defined as requiring:
1) active chronic skin lesions for >=3 months either on the face (eg, lupus pernio) or elsewhere on the body (typically indurated lesions consisting of papules, nodules and/or plaques) that have not resolved on current systemic and/or local therapy (ie, intralesional injections). Subjects, excluding those with only lupus pernio facial lesions confirmed by a dermatologist, will be required to have a skin biopsy, performed at screening or between the screening and baseline (Week 0) visit, which is diagnostic of sarcoidosis, AND
2) have either:
* a single lesion of >=2 cm in longest dimension, OR
* multiple (3 or more) lesions with at least 1 lesion having a longest dimension of >=1 cm, AND
3) have an SPGA score >=2 (with an induration subscore >=1) at screening;3. Have been receiving treatment with oral corticosteroids (>=10 mg/day of prednisone or equivalent dose of corticosteroid) and/or 1 or more immunomodulators (eg, methotrexate, AZA, chloroquine, hydroxychloroquine, mycophenolate, or leflutamide) for >=3-month period immediately prior to screening. Subjects must be on a stable dose of these medications for >=4 weeks before screening. For those subjects taking OCS, the dose at the screening visit must be <= 25 mg of prednisone (or equivalent dose of corticosteroid). ;This is a selection from the inclusion criteria. For all inclusioncriteria see page 31 of the protocol

Exclusion criteria

1. Have a diagnosis of other significant respiratory disorder other than sarcoidosis that in the opinion of the investigator would complicate the evaluation of response to treatment.
2. Have a smoking history of >= 20 pack years.
3. Have received previous administration of a treatment with any other therapeutic agent targeted at reducing TNFα (eg, pentoxifylline, thalidomide, etanercept, adalimumab, certolizumab, infliximab, golimumab) or anakinra within 6 months or 5 half lives of the agent, whichever is longer, prior to the screening visit. Subjects who have previously received biologic anti TNFα agents outside of the above period are allowed to enter the study; however, their prior history of usage of biologic anti TNFα agents (type, dosage, response to treatment, and reason for cessation of treatment) should be recorded.
4. Have previously used cyclophosphamide.
5. Have previously used or received local therapy (including local injections) within 3 months before the screening visit or used or received treatment with prescription topical creams within 1 month before the screening visit for treatment of sarcoidosis skin lesions.
6. Have used any antibody (monoclonal or polyclonal) or antibody based (antibody fragment, etc.) agents <= 6 months or within 5 half lives of the biologic prior to the screening visit,

whichever is longer
7. Have experienced an anaphylactic reaction to latex.
8. Have known clinically significant pulmonary hypertension and are receiving vasodilator therapy (eg, calcium channel blockers, prostacyclin or prostacyclin analogs, nitric oxide, adenosine).
9. Have participated in the acute phase of a pulmonary rehabilitation program within 4 weeks prior to the screening visit or plan to participate in pulmonary rehabilitation during the study.
10. Have concomitant diagnosis or any history of CHF, including medically controlled CHF, severe right-sided heart failure (ie cor pulmonale).
11. Have current signs or symptoms of infection or history of serious infection (eg, sepsis, pneumonia, or pyelonephritis), including any infection requiring hospitalization or IV antibiotics, for 3 months prior to screening. Established nonserious infections (eg, acute upper respiratory tract infection, simple urinary tract infection) need not be considered exclusionary at the discretion of the investigator.
12. Have a history of latent or active granulomatous infection, including histoplasmosis or coccidioidomycosis, prior to screening. Have signs and symptoms or a history of latent or active granulomatous infection (including TB or aspergilloma).
13. Have history of known demyelinating diseases, such as multiple sclerosis.
14 Have any known malignancy or have a history of malignancy (with the exception of basal cell carcinoma, squamous cell carcinoma in situ of the skin, or cervical carcinoma in situ that has been treated with no evidence of recurrence within 5 years prior to screening).
This is a selection from the ecclusion criteria. For all exclusioncriteria see page 33 of the protocol.

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: Recruitment stopped

Start date (anticipated):	18-05-2010
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Product type:	Medicine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	29-07-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-12-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-12-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-12-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-02-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	

Date:	03-03-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-05-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-07-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-08-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-12-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-01-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-02-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-02-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	10-03-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-04-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-05-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-06-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-06-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-07-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-07-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-09-2011

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-12-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-08-2012
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	EUCTR2009-010714-30-NL
CCMO	NL28640.078.09