A multiple-dose, subject- and investigator-blinded, placebo-controlled, parallel design study to assess the efficacy, safety, and tolerability of ACZ885 (canakinumab) in patients with pulmonary sarcoidosis

Published: 20-07-2016
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON46232

Source
ToetsingOnline

Brief title
CACZ885X2205

Condition

- Respiratory tract infections

Synonym
pulmonay sarcoidosis

Research involving

Human

Sponsors and support

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

Intervention

Keyword: ACZ885, efficacy, pulmonary sarcoidosis, safety

Outcome measures

Primary outcome

FVC (forced vital capacity)

Secondary outcome

SUVmax (maximum standardized uptake value) in nodules

Lung function tests

HRCT

6MWT (6-minute walk test) distance

PET scan

Safety and tolerability of ACZ885

Study description

Background summary

Chronic sarcoidosis is a systemic disease characterized by development of granulomas, inflammation and accompanying fibrotic tissue reactions. Although any organ can be affected, most common disease manifestations are found in lung, skin, and eye tissues.

IL-1* is known to induce and enhance granuloma formation in vitro and in vivo and to be involved in associated anergy.Thus, IL-1* represents a potential therapeutic target for sarcoidosis.

There are no approved therapies for sarcoidosis

Study objective

This study is designed as a proof-of-concept to assess if inhibition of IL-1*
by canakinumab
will improve lung function in association with attenuation of tissue
inflammation in patients
with chronic sarcoidosis, therefore allowing further development of the
compound for treatment of this disease population

Study design

First part: screening, max 40 days
Second part: treatment phase: 24 weeks
Third part: Follow up part; 8 weeks

Intervention

ACZ885 or placebo

Study burden and risks

Study period 9,5 month, 9 visits 2-4 hour

Physical examination: 9 times
Questionnaires:
KSQ (Kings Sarcoidosis Questionnaire), 8 times
FACIT-F (Functional Assessment of Chronic Illness Treatment-Fatigue), 8 times
MMRC (Modified Medical Research Council), twice
Borg Questionnaire: 9 times
Vital signs: 9x
S.c. injections (IMP administration): 12x
Bloodsampling: 9 times, 39 ml per draw, 350 ml total
Urine sampling: 1x
Pregnancy test: 3x (urine 2x, serum 1x)
Lungfunction test: 9x
PET/CT scan twice (fasted)
HRCT/CT scan: twice
ECG: 5 times
6MWT (6-minute walk test): 9 times

Optional:
Pharmcogenetic sub study (6 ml): once
Skin biopt; twice

Contacts

Public
Novartis

Raapopseweg 1
Arnhem 6824 DP
NL
Scientific
Novartis

Raapopseweg 1
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Disease duration of *1 year
- Clinically active disease demonstated either by a biopsy (any organ) or by bronchoalveolar lavage, patients must also have all of the following criteria:
- MMRC dyspnea scale * 1
- Threshold FVC 50 - 90% of predicted
- Evidence of parenchymal lung involvement by HRCT at screening or by historical radiological evidence
- Male and female subjects ages 18 to 80 years of age weighting at least 50 kg

Exclusion criteria

- Forced vital capacity (FVC) < 50% of predicted
- Any conditions or significant medical problems which in the opinion of the investigator immunocompromises the patient and/ or places the patient at unacceptable risk for immunomodulatory therapy, such as:
- Absolute neutrophil count (ANC) < LLN (1,500/*l)
- Platelets < LLN (75.0 x 109/L)
- Any active or recurrent bacterial, fungal (with exception of onychomycosis) or viral infection
- Presence of human immunodeficiency virus (HIV)infection, active hepatitis B or hepatitis C infections
- Presence of active or latent tuberculosis (TB) established during screening
- Clinical evidence or history of multiple sclerosis or other demyelinating diseases, or Felty*s syndrome

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):	22-12-2016
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ilaris

Generic name:	canakunimab
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	20-07-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-09-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-10-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-08-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-09-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-09-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-09-2018

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	EUCTR2016-001255-49-NL
ClinicalTrials.gov	NCT02888080
CCMO	NL58131.100.16