Low dose dexamethasone in newly diagnosed sarcoidosis

Published: 11-04-2013
Last updated: 24-04-2024

The main objective of this intervention study is to assess the effects of low-dose dexamethasone therapy on the quality of life of newly diagnosed sarcoidosis patientsThe secondary objectives are to assess the effects of low-dose dexamethasone...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON40492

Source
ToetsingOnline

Brief title
DEXSAR-trial

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Besnier-Boeck disease, sarcoidosis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: ZonMW,Achema onderzoeksfonds,Achmea onderzoeksfonds,Sarcoidose Belangenvereniging Nederland,Zorgonderzoek Nederland (ZON)

Intervention

Keyword: Dexamethasone, Quality of life, Sarcoidosis

Outcome measures

Primary outcome

- Health-related quality of life measured by SF-36 (subscale physical functioning)

Secondary outcome

Total medical resource utilisation

- Work productivity

- Cost-utility from a societal perspective

- Depression

- Fatigue

- Quality of sleep

- Cytokine profiles in plasma

- Disease progression

Study description

Background summary

Sarcoidosis is a rare disease that leads to a significantly reduced quality of life and productivity loss in young adults. There is inflammatory activity in multiple organs, often the lungs. There is no curative therapy, but symptoms can be suppressed with anti-inflammatory drugs. However, 90% of patients receive in the first months after diagnosis no therapy. These patients have a high degree of inflammatory activity and debilitating symptoms of fatigue, malaise and pain

This study examines whether early treatment at low cost leads to relief of symptoms, increase in quality of life, reduced health care costs and increased

work productivity. The results will contribute to new guidelines.

Study objective

The main objective of this intervention study is to assess the effects of low-dose dexamethasone therapy on the quality of life of newly diagnosed sarcoidosis patients

The secondary objectives are to assess the effects of low-dose dexamethasone therapy on (1) the total medical costs and work productivity of this population, (2) depression, fatigue and sleep quality, (3) the inflammatory profile and (4) disease progression and the need for additional pharmacotherapy

Study design

Prospective, randomized, double-blind, placebo controlled intervention study.

Intervention

Patients will be assigned to either 1 mg dexamethasone once daily for 180 days, or placebo once daily for 180 days.

Study burden and risks

Participation in this study requires per patient one additional hospital visit and one additional vena puncture and blood sample during that visit; all further visits and vena punctures are in conformance with standard sarcoidosis care. During these standard hospital visits one additional blood sample will be taken for this study (no additional vena puncture).

Patients participating in this study will be required to complete 6 questionnaires every 3 months during the first year of the study, and 6 questionnaires every 6 months during the second year of the study.

The intervention consists of once daily oral dexamethasone 1 mg or placebo during 180 days. A dose of 1 mg dexamethasone corresponds to a prednisone equivalent of 6.5 mg. There is substantial evidence that this dose can be safely administered during 6 months, without significant risk of bone-related, gastro-intestinal, cardiovascular or psychiatric adverse events.
If the present study shows that low dose dexamethasone in early sarcoidosis can improve quality of life in the first months after diagnosis this could have a large impact on the individual, social, and economic consequences of this disease.

Contacts

Public
Sint Antonius Ziekenhuis

Koekoekslaan 1
Nieuwegein 3435CM
NL
Scientific
Sint Antonius Ziekenhuis

Koekoekslaan 1
Nieuwegein 3435CM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Diagnosis of sarcoidosis conforming with ATS criteria (confirmed by histology or cytology) in the past 6 months
-Age between 18 and 60 years
-No affected organ requiring high dose immunosuppressive therapy
-SF-36 subscale physical functioning (SF-36 PF) score * 70 points

Exclusion criteria

-Allergy to corticosteroids
-Diagnosis of glaucoma
-Diagnosis of osteoporosis or history of fractures

-History of gastric ulcera in the past 12 months
-Current use of NSAIDs without co-prescription of a PPI
-Current use of potent inducer of cytochrome P450 liver enzymes (carbamazepin, fenytoin, rifampicin)
-Obesity (BMI > 30)
-Pregnancy or lactation

Study design

Design

Study phase:	4
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):	01-11-2013
Enrollment:	76
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dexamethasone
Generic name:	Dexamethasone
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	11-04-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-05-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-01-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-07-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-09-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-09-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-12-2014
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	EUCTR2013-000242-18-NL
CCMO	NL43685.100.13