Patients with axial spondyloarthritis and high disease activity treating with systemic glucocorticoids: a double-blinded randomised controlled trial

Published: 18-11-2021
Last updated: 04-04-2024

To investigate the potential role of systemic glucocorticoids in patient with axial spondylarthritis with high disease activity.

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON52017

Source
ToetsingOnline

Brief title
Intramuscular glucocorticoid for axial spondylarthritis (SPADE study)

Condition

- Joint disorders

Synonym
axial spondylarthritis, Bechterew's disease

Research involving
Human

Sponsors and support

Primary sponsor: Franciscus Gasthuis & Vlietland
Source(s) of monetary or material Support: subsidie voorziening Research Raad van

Bestuur Franciscus Gasthuis & Vlietland

Intervention

Keyword: axial spondylarthritis, glucocorticoids

Outcome measures

Primary outcome

The primary endpoint is the change in ASDAS between baseline and week 6.

Secondary outcome

Addition:

The primary endpoint is the change in ASDAS between baseline and week 3.

Secondary endpoints are change in ASDAS between baseline and week 6 or week 12;

number of patients achieving clinically relevant change, complete remission of

low disease activity (respectively (*ASDAS >=1.1, ASDAS <1.3, ASDAS <2.1)showing

clinically important improvement (*ASDAS >=1.1); change in CRP, BASDAI, BASFI,

patient global assessment and NRS between baseline and week 3, 6 or 12.

Study description

Background summary

The use of systemic glucocorticoids with axial spondylarthritis is discouraged in the ASAS-EULAR recommendations. However, new data suggesting a potential role for systemic glucocorticoid for patient with axial spondylarthritis.

Study objective

To investigate the potential role of systemic glucocorticoids in patient with axial spondylarthritis with high disease activity.

Study design

This will be a double-blinded, randomized controlled study in the outpatients

clinics of Franciscus Gasthuis & Vlietland Group. Patients willing to participate will be randomised into two groups, receiving either corticosteroid of placebo intramuscular injection. Comparisons in disease activity scores will be made between the two groups at baseline, week 3, week 6 and week 12.

Intervention

The intervention group will receive a single intramuscular dose of methylprednisolone 120mg. The control group will receive a single intramuscular dose of isotonic saline in the same volume, i.e. three millilitres.

Study burden and risks

In daily practice rheumatologists sometimes already use systemic glucocorticoids for patients with axial spondylarthritis with high disease activity. Few risks are to be expected because of the single administration and the low dosage of methylprednisolone. One hospital visit for injection, two extra blood samples and four telephonic evaluations are needed.

Contacts

Public
Franciscus Gasthuis & Vlietland

Kleiweg 500
Rotterdam 3045PM
NL
Scientific
Franciscus Gasthuis & Vlietland

Kleiweg 500
Rotterdam 3045PM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Meeting the ASAS classification criteria for axial spondylarthritis
Age 18-64 years
ASDAS >=2.1
Failure of standard treatment, meaning
- taking two different NSAIDs in maximum dosage over 4 weeks in total; or
- use of the same biological for at least 12 weeks
Ability to independently answer Dutch questionnaires
Given informed consent

Exclusion criteria

Starting or switching a biological <12 weeks ago
Concomitant disease that requires treatment with systemic GC (e.g. malignancy, chronic obstructive pulmonary disease)
Absolute contra-indications for corticosteroids (e.g. systemic infection, peptic ulcer disease)
Allergy to corticosteroids
Diabetes mellitus
Pregnancy or lactating female
Cognitive impairment
Participation in other medical trial
Language barrier

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2023
Enrollment:	38
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Depo-Medrone
Generic name:	Methylprednisolone acetate
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	18-11-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	22-11-2022
Application type:	Amendment
Review commission:	METC NedMec

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	EUCTR2021-001638-20-NL
CCMO	NL76576.041.21