Evidence-Based Mindset & Physical Therapy for Add-on Treatment of Active Axial Spondyloarthritis: Safety and Efficacy

Published: 11-02-2016
Last updated: 19-04-2024

To investigate whether an add-on mindset & physical therapy program based on the *Wim Hof Method* can safely and efficaciously be applied in patients with active axial spondyloarthritis.

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

Summary

ID

NL-OMON43901

Source
ToetsingOnline

Brief title
axSpA Add-on Tx

Condition

- Autoimmune disorders
- Joint disorders

Synonym
Axial Spondyloarthritis, Bechterew

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Add-on therapy, Auto Immune Disease, Spndyloarthritis, Wim Hof Method

Outcome measures

Primary outcome

Safety evaluation of the program is the primary aim of the study, and

therefore, the primary outcome measure is chosen to detect changes at the level

of severity of the axial spondyloarthritis (axSpA) using clinical parameters.

Secondary outcome

- Difference in CRP between baseline and week 8

- Difference in circulating cytokines between baseline and week 8

- Change in Ankylosing Spondylitis Disease Activity Score (ASDAS)

- Change in other serum inflammation biomarkers (ESR, calprotectin)

- Change in quality of life as measured by the SF-36, the EQ-5D

- Change in depressive symptoms as measured by the Beck Depression Inventory

(BDI-II)

- Predictive role of generalized and specific outcome expectancies (EPQ-N,

LOT-R, VAS scales)

Study description

Background summary

Recent investigations suggest that, through certain concentration/meditation

techniques, it is possible to modulate autonomic activity. The results of a recent randomized controlled trial investigating the *Wim Hof Method* have shown a direct biological effect on in-vivo cytokine production and are strongly encouraging the clinical evaluation of the technique*s efficacy in immune-mediated inflammatory diseases.

Study objective

To investigate whether an add-on mindset & physical therapy program based on the *Wim Hof Method* can safely and efficaciously be applied in patients with active axial spondyloarthritis.

Study design

Prospective open-label randomized controlled trial, safety and efficacy.

Intervention

A 60-day training program of add-on mindset and physical therapy for axial spondyloarthritis, using the methodology as designed and instructed by Wim Hof. It involves breathing techniques, training of mindset and concentration, and gradual cold exposure.

Study burden and risks

The program starts with a 30-days training course introduced by weekend-sessions (burden 8 hours). Subsequently there will be eight evening sessions (burden 1-2hours) and patients will be instructed to do a daily 30-minute training session at home. During the four week follow-up study period there will be one evening session per week led by the instructor (burden 1-2hours per session). Additionally patients are instructed to continue the 30-minute daily practice session at least during the first 60 days or as long as deemed useful to the patient. Based on empirical data we do not anticipate treatment related risks related to participation in this study, but it is possible (though unlikely) that the patient*s condition might worsen. Furthermore, patients with axSpA are typically young adults with little or no comorbidity, hence representing a relatively safe study group. The benefits seem to outweigh the risks as patient*s condition may improve significantly within 60 days.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1100DD
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1100DD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Clinical diagnosis of axSpA as assessed by the treating rheumatologist fulfilling the ASAS classification for axial SpA [Rudwaleit 2009]
-Between 18 and 55 years of age at screening
-Active disease as defined by an Ankylosing Spondylitis Disease Activity Score (ASDAS) of >2.1 and a CRP value of *5 at the screening visit.
-Ability and willingness to participate to the study and give written informed consent.

Exclusion criteria

-Patients who cannot give written consent or, in the opinion of the investigator, cannot comply to the requirements of the study protocol. Significant comorbidity, including a cardiac, renal, hepatic, neurological, metabolic or any other severe disease, which in the opinion of the investigator may interfere with the study or lead to deleterious effects for the patient.
-Recent history of (or persistent) infection requiring hospitalization or antibiotic treatment within 4 weeks of baseline.
-If female, patient should not be pregnant. A urine pregnancy-test will be performed at

screening and has to be negative.
-Initiation of treatment with corticosteroids or DMARDs (synthetic and biologic) within 8 weeks before screening.
-Initiation of treatment with NSAID within 2 weeks before screening.
-Variation of the treatment doses within 6 weeks of screening.
-Intra-articular injection with corticosteroids within 4 weeks prior to screening.
-Daily doses of systemic corticosteroids exceeding the equivalent of 10 mg prednisolone per day.
-Use of other drugs and treatments that may affect the evaluation of systemic inflammation as judged by the investigator.
-Cardiovascular risk factors such as a personal history of cardiovascular disease, familial history of major adverse cardiovascular events (MACE) at age younger than 55 yrs, hypercholesterolemia and stroke.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-04-2016
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	11-02-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	26-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL55398.018.15