Acupuncture for moderate Chronic Obstructive Pulmonary Disease (COPD)

Published: 20-08-2012
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To investigate the effectiveness and cost-effectiveness of acupuncture treatment combined with standard care compared to standard care alone.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON37079

Source
ToetsingOnline

Brief title
Acupuncture for moderate chronic COPD

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic bonchitis/emphysema - chronic obstructive lung pathways

Research involving
Human

Sponsors and support

Primary sponsor: Nederlandse Artsen Acupunctuur Vereniging
Source(s) of monetary or material Support: hoofdzakelijk via eigen budget plus hopelijk de Astmafonds

Intervention

Keyword: acupuncture, comparative, copd, randomised

Outcome measures

Primary outcome

(1) Forced Expiratory Volume in 1 second (FEV1) and Forced Vital Capacity

(FVC), the 2 scores combined as Forced Expiratory Ratio (FER=FEV/FVC),

reflecting the lung function

(2) Clinical COPD Questionnaire (CCQ), reflecting the overall health over the 3

domains, of symptoms/function/mental status.

Secondary outcome

(1) Physical endurance recorded in 6 Minute Walk Distance (6MWD)

(2) Inflammation factor (CRP)

(3) Cost-Effectiveness analysis

Study description

Background summary

Chronic obstructive pulmonary disease (COPD) and Asthma belong to major disabling lung diseases worldwide. Due to smoking and aging, the COPD (emphysema and chronic bronchitis) incidence will increase strongly in the near future and as a consequence it will have a large impact on the Dutch Healthcare costs. In the Netherlands, recently CAM-modalities are "mentioned" in the National COPD-treatments guideline (LAN). The Dutch Medical Acupuncture Society (NAAV) scientific committee has the intention to evaluate the additional value of acupuncture treatment as performed within the context of the regular GP-practices.

Study objective

To investigate the effectiveness and cost-effectiveness of acupuncture

treatment combined with standard care compared to standard care alone.

Study design

A 2-arm pragmatic randomised controlled multi-centre trial of 12 week live-phase and 3 months follow-up time. The estimated sample size required to detect an appropriate clinical difference at a power of 90 % and 5 % significance is 100 participants. In order to mimic the *real-world* practice blinding is not necessary, our data analysis will be an *Intention-to-Treat* one.

Intervention

Patients allocated to the acupuncture group will receive the treatment at least once a week for the following 12 weeks, in addition to taking their daily medication. The control group will receive standard care only. All regular activities, like taking exercises will not be interrupted.

Study burden and risks

Not applicable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

COPD GOLD 1 and 2 categories lungpatients

Exclusion criteria

severe lung diseases

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:	Will not start
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO Date:	20-08-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL41002.028.12