Acupuncture for Nasal Congestion in Allergic Rhinitis: An Open-Label, Randomized, Monocenter Trial (ANCAR Trial)

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To evaluate the effects of an acupuncture treatment protocol for nasal congestion in AR.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Interventional

Summary

ID

NL-OMON53405

Source
ToetsingOnline

Brief title
Acupuncture for Nasal Congestion in Allergic Rhinitis (ANCAR)

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
nasal blockage, Nasal obstruction

Research involving
Human

Sponsors and support

Primary sponsor: Mermaid Medicine®
Source(s) of monetary or material Support: DocSave® (www.docsave.com) levert gratis alle benodigde Cloud & Dragon® acupunctuurnaalden, NonDolens® medische

wegwerphandschoenen en acuBox® naaldcontainers (totale waarde is 240 ¤).,Partly by GoFundMe;patients Mermaid Medicine/family/friends/colleagues;Nederlandse Vereniging voor Acupunctuur (NVA is a non-profit organisation);for the rest own finances sponsor (J.M. Vermeulen).

Intervention

Keyword: Acupuncture, Allergic rhinitis, Nasal congestion, Randomized

Outcome measures

Primary outcome

VAS to compare the effects of acupuncture with azelastine nasal spray (Carelastin®) on nasal congestion in AR after 6 weeks of treatments (VAS, 0 = no nasal congestion, and 10 = most severe nasal congestion). The VAS score improvement defined as any decrease in VAS score at 6 weeks of treatments compared to entry VAS score (before starting treatment).

Secondary outcome

• VAS, Adapted NOSE and PNIF to compare the effects of acupuncture with azelastine nasal spray (Carelastin®) on nasal congestion in AR after different visits of treatments. In terms of improvement and the quantity of improvement.

• VAS to assess the effects of acupuncture on other nasal and ocular signs and symptoms in AR (sneezing, nasal itching, rhinorrhea, itchy eyes, red eyes, burning eyes and watery eyes).

• Adapted NOSE with novel additions regarding general health, concentration, energy level and ear pressure equalization in diving and flying.

Study description

Background summary

Worldwide more than approximately 500 million people suffer from AR[1, 2] (30% of the Dutch population (Mylan Update, 2018[2]) and its prevalence is expanding[1]. Nasal congestion (i.e. reversible mucosal congestion [3]/nasal mucosal obstruction[4]) is one of the most general and bothersome symptoms in rhinitis[5, 6] and is associated with other medical conditions such as rhinosinusitis and otitis media[7, 8]. This study is relevant as in addition to the high global occurrence of AR, this disorder has substantial effects on the quality of life (QOL) (e.g. during sleep and work)[9]. AR is related to high direct medical costs (mainly prescriptions of medications and outpatient visits) and indirect economic costs (including productivity decrease)[8, 10, 11]. Current medications are undesirable due to their side-effects (such as sedation in the case of intranasal antihistamines (INAH)[11].
Acupuncture for AR in general can be considered as safe and can be seen as a potential remedial blueprint for nasal congestion[12]. Evidence supported that acupuncture is clinically used for signs and symptoms of nose disorders, such as nasal congestion, with effectiveness, but whether acupuncture has immediate, post-treatment and long-term effects on specifically nasal congestion in AR is not verified by strictly designed clinical study.
The ANCAR trial aims to evaluate the effects of an acupuncture treatment protocol for nasal congestion in AR compare to azelastine nasal spray. A standard treatment protocol with a fixed set of acupuncture points has been stablished - to be as scientific as possible from Western medical viewpoint - and this selection of acupuncture points can be seen as a solid and profound approach from which every AR patient may benefit. This standard set opens the nose and affects the underlying energetic imbalance and immunity at the same time to maintain its nose opening effect (i.e. to prevent recurrence of the complaint).
The acupuncture protocol concerns 8 treatments during 6 weeks (i.e. 2 treatments per week during the first 2 weeks and 1 treatment per week in the consecutive 4 weeks). The positive effects of this treatment protocol (such as improvement QOL), may result in more confidence in the direct, post-treatment and long-term effects of acupuncture and lead to more acceptance of acupuncture as a solid treatment option for nasal congestion in AR instead of using an INAH spray.

References: See page 37 ANCAR Research Protocol.

Study objective

To evaluate the effects of an acupuncture treatment protocol for nasal congestion in AR.

Study design

The trial is designed as an open-label, randomised, monocenter trial. All eligible patients will be randomized (1:1) between two arms (open-label), i.e.,

arm A (Acupuncture) and arm B (Control).
Short-Term-Intervention RCT: 6 weeks treatment protocol with measurements before and at 15 minutes after the 1st acupuncture treatment/1st azelastine usage (to compare the immediate effects), at 15 minutes after the 2nd - 8th acupuncture treatment and final usage of azelastine (= parallel to 8th acupuncture treatment = post-treatment), then following the treatment period after 2 weeks and 2 months (to compare the long-term effects). The accrual expected to be 60 days.

Intervention

To compare the effects of acupuncture with azelastine nasal spray (Carelastin®) on nasal congestion in AR based on VAS (Visual Analog Scale) score.

Study burden and risks

Burden: Visits to Mermaid Medicine® (time investment), completing VAS and Adapted NOSE questionnaires, undergoing PNIF-measurements.

Participation in the study has a negligible risk. Acupuncture for AR in general can be considered as safe[20, 21]. No fatal or serious events are reported[20, 21], solely mild side-effects such as pain, papules, pruritus, subcutaneous hematomas, dizziness, numbness and headache[20].
Side-effects Carelastin® azelastine nasal spray: bitter taste, drowsiness[11, 27], headache and burning sensation in the nose[27].
Benefits: Acupuncture and Carelastin® azelastine nasal spray can reduce AR symptoms.

References: See pages 37-38 ANCAR Research Protocol.

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

• Diagnosed AR by a physician.
• Have one of the AR types: seasonal (SAR) or perennial (PAR) or mixed (MAR) allergic rhinitis.
• VAS nasal congestion: from 3-10.
• Age: from 18 years.
• Signed Informed Consent.

Exclusion criteria

• COVID-19.
• Acute common cold.
• Influenza.
• Fever (38°C or higher).
• Acute nasal trauma (such as a fracture and epistaxis).
• Irreversible nasal blockages (such as septum deviation, concha bullosa, polyps and cysts).
• Nasal and sinus cancer.
• Pregnancy or planning for pregnancy.
• Consumed decongestions, antihistamines, antibiotics or corticosteroids within 2 weeks before the RCT.
• Received acupuncture, Chinese herbal medicine or another complementary treatment within 2 weeks before the RCT.
• Received immunotherapy within 2 weeks before the RCT.
• Patients refusing or unable to sign Informed Consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-04-2023
Enrollment:	62
Type:	Actual

Ethics review

Approved WMO Date:	06-03-2023
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	06-04-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	28-07-2023
Application type:	Amendment
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
ClinicalTrials.gov	NCT05709977
CCMO	NL82046.028.23

Study results

Date completed: 22-12-2023

Summary results
Trial ended prematurely