Trial Description

Title

Acupressure for Seasonal Allergic Rhinitis - a randomized controlled exploratory trial

Trial Acronym

ACUPRES

URL of the trial

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Brief Summary in Lay Language

Seasonal Allergic Rhinitis (SAR) is a widespread disease with a prevalence of 20% in industrialized nations. In preliminary studies acupuncture turned out to be a valid and safe treatment option for patients with SAR.
ACUPRES is a clinical study performed at the Charité Institute for Social Medicine, Epidemiology and Health Economics investigating the effects of self-administered Body-Acupressure on disease related quality of life and intake of disease-specific medication in patients with hay fever (Season Allergic Rhinitis, SAR).
Main inclusion criteria are (amongst others): Age 18-60, Diagnosis hay fever on grasses and birch pollen (since more than two 2 years), no Asthma and / or mild forms of atopic dermatitis.
After randomization, participants of the acupressure group receive an acupressure training and are instructed to practice this self-acupressure according to scheme on a daily basis during the intervention-period of 4 weeks. In addition, participants of this group can use anti-allergic rescue medication (Antihistamines, Cortisone) if needed. The control group is instructed to only use anti-allergic rescue medication for the period of 8 weeks. After week 8, participants of this group can also participate in an acupressure-training.

Brief Summary in Scientific Language

Background: Seasonal Allergic Rhinitis (SAR) is a widespread disease with a prevalence of 20% in industrialized nations. In previous studies acupuncture was proved as effective and safe treatment option for patients with SAR. To date, there are no studies on feasibility and effects of self-administered body-acupressure as a self-ministered-tool in SAR patients.

Objectives: The goal of this study is to evaluate the effects of self-administered body acupressure plus rescue medication compared to rescue medication alone on disease related quality of life and intake of disease-specific medication in patients with SAR.

Design: Two-armed, mono-center randomized controlled exploratory trial. In addition, focus-groups are planned within a qualitative sub-study.

Participants: 40 to 60 participants aged 18-60 with diagnosed SAR (since more than two 2 years) on grasses and birch pollen will be included in the study.

Intervention: After randomization, participants of the acupressure group receive an acupressure training and are instructed to practice standardized self-acupressure according on a daily basis during the intervention-period of 4 weeks. In addition, participants of this group can use anti-allergic rescue medication (Antihistamines, Cortisone) if needed. Patients of the control group are instructed to use only anti-allergic rescue medication for the period of 8 weeks. After week 8, participants of this group can also participate in an acupressure-training.

Outcome-parameters: Outcome-parameters are being assessed at baseline, after week 4 and 8 weeks. Primary outcome-parameters are: disease-related quality of life [Rhinitis Quality of Life Questionnaire (RQLQ)] and the use of anti-allergic medication [Rescue Medication Score (RMS)].

Perspective: The results of this trial will provide first information on the effects of self-administered body acupressure in SAR patients and will be used as basis for further confirmatory studies.

Organizational Data

- DRKS-ID: **DRKS00014310**
- Date of Registration in DRKS: **2018/04/24**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EA1/033/18 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **J30.1 - Allergic rhinitis due to pollen**

Interventions/Observational Groups

- Arm 1: **Acupressure Group:**

  Participants of the acupressure group are instructed to practice self-acupressure on pre-defined acupressure points (5 points) over a period of four weeks. Acupressure-points are to be pressed for at least 4 minutes per point (2 x 10 minutes/day or 1 x 20minutes).
  Acupressure points being used in this study are selected following the expert

**opinion of the ACUSAR study (Brinkhaus et al, 2013).
In addition, anti-allergic rescue medication is being provided to participants of both groups: If the SAR-symptoms cannot sufficiently be controlled by Antihistamines (maximum 2 x 10 mg per day), oral corticosteroids can be taken.**

- Arm 2: **Control-Group with anti-allergic rescue medication only**

  Participants of the control group are instructed to only use anti-allergic rescue medication (Antihistamine Cetirizin max. 2 x 10mg/day, oral corticosteroids if needed) for the period of 8 weeks. After week 8, participants of this group can also participate in an acupressure-training and receive further individual advice by telephone.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **data analyst**
- Control: **Control group receives no treatment**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

**- Disease related quality of life (Rhinitis Quality of Life Questionnaire – RQLQ). Data to be collected in questionnaire and diary at baseline and after week 2, 4 and 8.
- Intake of disease related medication (Quantity and Frequency of Rescue Medication (Cetirizin, Corticosteroid): data to be collected daily in the diary during week 1 to 4 and in week 8.**

- Quantity and Frequency of Rescue Medication (Cetirizin, Corticosteroid). The Rescue Medication Score of the last month is being calculated accordingly: 0-3: 0=no Cetirizin, 1 = Cetirizin 1x10mg/day, 2= Cetirizin 2x10mg/day, 3= oral Corticosteroid.

Secondary Outcome

Data collected in intervention group and control group:

- General health-related Quality of Life (SF-36) at baseline, after week 4 and week 8
- Questions on autonomic regulation (Havelhöhe trait-inventory of autonomic regulation, THKF) at baseline, after week 4 and week 8
- Days of incapacity for work due to SAR between Baseline and week 4 / week 8
- VAS symptom score nasal, non-nasal and overall symptoms on SAR between week 1-4 and in week 8 1x/week
- Disease-related direct and indirect costs (social / economic perspective)

Data captured only in the intervention group:

- Safety of treatment: assessment of adverse events in week 1 to 4 and in week 8
- Study-doctors and Patients perception of the effectiveness of acupressure in general and related to SAR after week 4
- Satisfaction of the patient with acupressure after week 4 and after week 8
- Intensity and frequency of acupressure, data collected in a diary in week 1-4 and in week 8
- Quality control of acupressure in telephone interview or visit in week 1 and 3
- focus groups are planned within a qualitative sub-study, collecting data on patients expectations, the effect of the treatment and the patients' appreciation.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Charité Universitätsmedizin Berlin, Institut für Sozialmedizin, Epidemiologie und Gesundheitsökonomie, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/04/18**
- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **60 Years**

Additional Inclusion Criteria

1. Age 18-60
2. clinical diagnosis SAR and positive skin PRICK Test or RAST Test (minimum class 2) on grasses and birch pollen for more than 2 years
2.1. mean SAR symptoms in the last season: Visual Analogue Scale (VAS) ≥30 mm, ≤70mm
2.2. mean SAR symptoms in the last 7 days: Visual Analogue Scale (VAS) ≥30 mm, ≤70mm
2.3. existence of a positive Skin-Prick-Test or RAST (minimum Class 2)
3. Given linguistic and intellectual ability to fill diaries and questionnaires
4. medical indication for intake of oral Antihistamines and / or Corticosteroids as anti-allergic treatment
5. oral and written declaration of consent

Exclusion criteria

1. Perennial Allergic Rhinitis or other forms of chronic Rhinitis
2. Allergic Asthma and / or mild to severe forms of Atopic Dermatitis
3. Other pulmonary disease, especially Tuberclosis
4. Autoimmune-Disease
5. Sever acute and / or chronic organic or psychatric disease
6. Medical history with anaphylactic shock
7. Intolerance of Antihistamines and / or Corticosteroids
8. specific immunotherapy / desensitizing therapy planned or carried out during study period
9. Pregnancy or nursing
10. Acupuncture treatment, acupressure and / or other complementary medicine treatments for SAR planned or carried out during study period
11. Participation in an other clinical study on SAR

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*