A clinical investigation of Kinetic Oscillation Stimulation by the Chordate System S101 in the treatment of Non Allergic Rhinitis (KOSNAR)

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Objectives are to evaluate the efficacy of the procedure in reducing disease specific symptoms such as nasal congestion, rhinorrhea, nasal itching and sneezing, but also to investigate the influence on quality of life, safety and tolerability.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50568

Source
ToetsingOnline

Brief title
Chordate System S101 Non Allergic Rhinitis Clinical Investigation

Condition

- Other condition

Synonym
continous sneezing, Non Alleric Rhinitis, running nose

Health condition

Non Allergic Rhinitis

Research involving

Human

Sponsors and support

Primary sponsor: Chordate medical AB
Source(s) of monetary or material Support: Chordate Medical AB

Intervention

Keyword: Non Allergic Rhinitis, Peak Nasal Inspiratory Flow

Outcome measures

Primary outcome

The primary performance endpoint is the responder rate based on the change in the weekly median nasal congestion score (taken from TNSS) from baseline to the 3 month follow-up visit

Secondary outcome

Responder rates based on the change from baseline to the other follow-up visits in the nasal congestion score (taken from TNSS)

* Change from baseline to each of the follow-up visits in weekly mean Total Nasal Symptom Score (TNSS)

* Change from baseline to each of the follow-up visits in Total Nasal Obstruction and Septoplasty Effectiveness (NOSE) Score

* Responder rates based on the change from baseline to each of the follow-up visits in each of the individual symptoms scores in the Nasal Obstruction and Septoplasty Effectiveness Scale (NOSE)

* Change from baseline to each of the follow-up visits in Peak Nasal Inspiratory Flow (PNIF)

* Patient assessment of change in their disease status

* Patient satisfaction

* Change from baseline to each of the follow-up visits in functional disability

and health-related quality of life, according to the EQ-5D-5L questionnaire

* Use of rescue medication

Study description

Background summary

Nasal obstruction is a very common disorder which can be caused by both anatomical and mucosal reasons. In the case of anatomical reasons septal deviation and other skeletal defects are causative. Mucosal disorders are due to a lot of underlying diseases of which allergic rhinitis, is the most common (1). When allergic rhinitis and infections are ruled out as underlying diseases the term non-allergic non-infectious rhinitis or simply non-allergic rhinitis (NAR) is used to describe rhinitis of unknown origin. In epidemiologic studies as much as 10-20 % of the population is found to fulfill these criteria*s of non-allergic rhinitis, i.e.no causative reason is found to the complaints although a thorough examination (2-3). Synonymously to NAR the term vaso-motor rhinitis (VMR) was earlier used. The most prominent symptom in NAR is nasal blockage but in some patients nasal hyper secretion is dominating. Histamine related symptoms like itching and sneezing are not seen. However, effects on quality of life can be very substantial (4-5). And treatment is mostly difficult to make successful although local corticosteroids can give relief to nasal blockage in NAR (6). Poor results in the treatment may be due to a multiple related etiology of NAR like occupation, hormones, drugs. Due to a lack of reliable immunological markers the role of the nerve system in the nasal cavity is of interest. Mechanisms behind the disease is thus to some extent obscure even if we know that there is some sort of imbalance in the neural regulation of the mucosal lining of the nose. The balance between sympathetic and parasympathetic control of the vessels and thereby an imbalance of the degree of nasal blockage is the ground for the term of *vaso-motor rhinitis*. Probably, interactions between the immune system and the nerve system contribute to nasal diseases therefore the activity of the nerve system is interesting in patients with NAR.

Study objective

Objectives are to evaluate the efficacy of the procedure in reducing disease specific symptoms such as nasal congestion, rhinorrhea, nasal itching and sneezing, but also to investigate the influence on quality of life, safety and

tolerability.

Study design

This is a double-blind, placebo-controlled, multi-center study in which patients diagnosed with non-allergic rhinitis will receive intranasal stimulation with the Chordate System at two occasions

Intervention

treatment with the Catheter A100 combined with the Chordate System S101).

Study burden and risks

Nature and extent of the burden and risks are described in the protocol on page 36 - 38 of the protocol

Contacts

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SE
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with persistent (>12w) symptoms of non-allergic rhinitis dominated by nasal congestion (± secretion) for an average of at least 1 h per day for at least 5 days during a period of 14 days.
2. Having nasal congestion as major symptom, and a median nasal congestion score of at least 2 (scale 0-3)
3. Male or female 18 * 65 years
4. Judged by the Investigator as suitable for participation in the study without safety concerns based on medical history and physical examination.
5. Willing and able to provide written informed consent prior to participation in the clinical investigation
6. Willing and able to comply with all study related procedures

Exclusion criteria

Patients with Allergic rhinitis, demonstrated by either positive skin prick test, Phadiatop or RAST during the last year.
2. Ongoing respiratory tract infection including nasal cavity at inclusion
3. Systemic steroid treatment less than 4 weeks before the inclusion in the study
4. Patients with a history of nasal surgery like: septoplasty, cosmetic surgery, conchal surgery or any other nasal surgery except closed reposition for nasal fracture during last year
5. History of frequent nose bleeds or a condition that increases the risk of excessive bleeding
6. Pronounced anterior septal deviation or other significant nasal pathology at endoscopic examination
7. Current malignancy of any kind
8. Known allergy to polyvinylchloride or medicinal liquid paraffin
9. Any disease, condition (medical or surgical) or drug or alcohol abuse which, in the opinion of the investigator, might compromise the study results, or would place the patient at increased risk.
10. Any implant with an electrical and/or neurostimulator device, including but not limited to cardiac pacemaker, defibrillator, vagal neurostimulator, deep brain stimulation, spinal stimulator, bone growth stimulator, or cochlear implant or any other implant in the head-, and neck region.
11. Previous treated with radiation on the face, head or neck regions
12. Female patients who are pregnant or become pregnant at any time from inclusion of the study until end of the 8 week follow-up visit

13. Received study drug in a clinical trial for an investigational drug within the previous 30 days, or 5 half-lives, whichever is longer

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-05-2018
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Chordate System S101
Registration:	No

Ethics review

Approved WMO Date:	08-03-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	29-07-2020
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	NL64268.018.18