

Does carrageenan nasal spray improve quality of life in patients with chronic rhinosinusitis?

Submission date 17/06/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/06/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/06/2017	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Chronic rhinosinusitis (CRS) is a disease that causes inflammation (swelling) in the sinus (inside the nose). This can block the airways and cause severe pain. Patients suffering from CRS report interruptions in their daily activities, well-being and quality of life. The main treatment for CRS is to use a topical nasal treatment that contain steroids (anti-inflammatory medications), usually as a spray. Using those treatments, as well as saline irrigation (a salt water rinse to wash out anything in the nose) has shown to improve the symptoms of CRS and improve quality of life in patients who have not been treated. Saline irrigation has been recommended to be used after surgery to promote healing. However, if this should be done as a nasal douche (sniffing the saline solution into one nostril and letting it run out) or nasal spray has not been determined. The steroid treatments have shown to be effective at reducing inflammation. Still, patients are not fully cured under this treatment. Carrageenan (a common food additive used as a thickener) nasal spray has been investigated in patients who have a common cold. It can increase the viscosity (thickness) if applied as a nasal spray, prolonging the moisture of the nasal mucosa. This requires more research to see how it works. This study evaluates the impact of a medical device, a carrageenan nasal spray, on quality of life in patients diagnosed with CRS.

Who can participate?

Adults aged 18 and older who are diagnosed with CRS.

What does the study involve?

Participants are allocated to groups. Those in the first group have not received treatment. The second group consists of participants who underwent functional endoscopic sinus surgery. In these two groups, participants are randomised to either receiving the treatment or the placebo (dummy treatment). All participants are given the study device and are asked to use it five times a day every two to three hours for 60 days. Participants fill out questionnaires prior to treatment, at 60 days and 90 days to assess their quality of life.

What are the possible benefits and risks of participating?

There are no notable benefits or risks with participating.

Where is the study run from?
Medical University of Vienna (Austria)

When is the study starting and how long is it expected to run for?
October 2016 to December 2019

Who is funding the study?
Medical University of Vienna (Austria)

Who is the main contact?
Dr Sven Schneider
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CRS-17

Study information

Scientific Title
Effects of carrageenan nasal spray as additive therapy on quality of life and clinical outcome in patients diagnosed with chronic rhinosinusitis

Study objectives

Carrageenan nasal spray significantly improves quality of life in Patients diagnosed with chronic rhinosinusitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee Medical University of Vienna, 19/05/2017, ref: 2254/2016

Study design

Prospective single-centre double-blind randomised controlled interventional trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

See additional files (in German)

Health condition(s) or problem(s) studied

Chronic Rhinosinusitis

Interventions

Patients diagnosed with chronic rhinosinusitis who did not receive any treatment in the past three months or patients diagnosed with chronic rhinosinusitis presenting for functional endoscopic sinus surgery are eligible to participate in this study. Participants are sorted to one of two groups. Those in the first group are the treatment naïve group. Those in the second group are participants who recently underwent functional endoscopic sinus surgery. In these two groups, patients are subsequently randomised to either receiving the intervention treatment or the control treatment. All participant receives a study device, however those in the control group have a placebo treatment. The study device is used five times a day at intervals of two to three hours for 60 days in each group. Randomisation of the study device are performed stratified, separately for the group of treatment naïve patients and the group of patients presenting for surgery.

Participants in the treatment naïve group receive treatment with topical steroids and saline irrigation according to the hospitals' standards. Additionally, patients receive the randomised study device. Therapy consisting of topical steroids, saline irrigation and study device will be applied for 60 days. Follow up time is 90 days and quality of life questionnaire SNOT-20 GAV are completed at time of enrollment, 60 days after enrollment and 90 days after enrollment.

Participants in the group presenting for surgery receive post operative treatment with topical steroids and saline irrigation according to the hospitals' standards. Additionally, participants receive the randomized study device. Therapy consisting of topical steroids, saline irrigation and study device will be applied for 60 days. Follow up time is 90 days and quality of life questionnaire SNOT-20 GAV will be asked at time of enrollment, 60 days after enrollment and 90 days after enrollment.

Intervention Type

Device

Primary outcome measure

Quality of life is measured using SNOT-20 GAV questionnaire at baseline, after 60 days of treatment and 30 days after completion of treatment.

Secondary outcome measures

1. Necessity of surgery in the treatment naive group will be evaluated 90 days after enrollment
2. Onset of improved quality of life will be evaluated after 60 days of treatment

Overall study start date

01/10/2016

Completion date

01/12/2019

Eligibility

Key inclusion criteria

1. Patients diagnosed with Chronic Rhinosinusitis who did not yet receive treatment and patients treated by functional endoscopic sinus surgery for the first time and have signed an informed consent form will be included in this study. If no medical treatment was applied in the last three months, patients are classified as treatment naive.
2. Chronic rhinosinusitis is diagnosed according to the clinical practice guidelines of the American Academy of Otolaryngology, Head and Neck Surgery. Patients meet the criteria when the following conditions are found:
 - 2.1. Twelve weeks or longer of two or more of the following signs and symptoms:
 - 2.1.1. Mucopurulent drainage (anterior, posterior, or both)
 - 2.1.2. Nasal obstruction (congestion)
 - 2.1.3. Facial pain-pressure-fullness or decreased sense of smell
 - 2.2. Inflammation is documented by one or more of the following findings:
 - 2.2.1. Purulent (not clear) mucus or edema in the middle meatus or anterior ethmoid region,
 - 2.2.2. Polyps in nasal cavity or the middle meatus, and/or
 - 2.2.3. Radiographic imaging showing inflammation of the paranasal sinuses
3. Ability to sign informed consent form
4. Signed informed consent form
5. Age over 18 years
6. Computed tomography scan showing signs of inflammation in the paranasal sinuses

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

220

Key exclusion criteria

1. Patients diagnoses with medical conditions like allergic rhinitis, cystic fibrosis, immunocompromised state, ciliary dyskinesia, acetylsalicylic acid intolerance or severe anatomic variations
2. Pregnant women and minors
3. Patients who received nasal corticosteroid therapy for Chronic Rhinosinusitis in the prior three months and not presenting for surgery will not be included
4. Patients intending to use other nasal sprays during the study period, patients not able to use a nasal spray every day
5. Patients who had an adverse reaction to seaweed products will not be included

Date of first enrolment

01/09/2017

Date of final enrolment

01/06/2019

Locations**Countries of recruitment**

Austria

Study participating centre**Medical Universitiy of Vienna**

Department of Otorhinolaryngology - Head and Neck Surgery

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Sponsor information**Organisation**

Medical University of Vienna

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Sponsor type

University/education

ROR

<https://ror.org/05n3x4p02>

Funder(s)**Funder type**

University/education

Funder Name

Medical University of Vienna

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal in December 2020.

Intention to publish date

31/12/2020

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be available upon request from sven.schneider@meduniwien.ac.at

IPD sharing plan summary

Not provided at time of registration