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

Submission date
17/06/2017

Recruitment status
No longer recruiting

Registration date
30/06/2017

Overall study status
Completed

Last Edited
30/06/2017

Condition category
Ear, Nose and Throat

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 if 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
sven.schneider@meduniwien.ac.at

Contact information

Type(s)
Scientific

Contact name
Dr Sven Schneider

ORCID ID
https://orcid.org/0000-0002-7631-3746

Contact details
Medical Universtiy of Vienna
Waehringer Gürtel 18-10
Vienna
Austria
1090

Additional identifiers

Protocol serial number
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

Study type(s)
Quality of life

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 naive patients and the group of patients presenting for surgery.

Participants in the treatment naive 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(s)
Quality of life is measured using SNOT-20 GAV questionnaire at baseline, after 60 days of treatment and 30 days after completion of treatment.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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 Universtiy of Vienna
Department of Otorhinolaryngology - Head and Neck Surgery
Waehringer Gürtel 18-20
Vienna
Austria
1090

Sponsor information

Organisation
Medical University of Vienna

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
University/education

Funder Name
Medical University of Vienna

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes