Effects of STB* wound dressing on nasal wound healing after radiofrequent coblation of the inferior turbinate

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In this study we will compare the therapeutic value of nasal saline irrigations only versus nasal saline irrigations combined with nasal application of STB* ointment in patients who received inferior turbinate coblation by radiofrequency (ITC-RF)....

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

Summary

ID

NL-OMON48357

Source
ToetsingOnline

Brief title
STB* wound dressing after coblation of the inferior turbinate

Condition

- Upper respiratory tract disorders (excl infections)
- Respiratory tract therapeutic procedures

Synonym
Inferior cocha/ inferior turbinate

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Dos Medical B.V.,Isala academie

Intervention

Keyword: Coblation, STB wound dressing, Turbinate, Woundhealing

Outcome measures

Primary outcome

Primary objective: is there a significant difference in the overall nasal VAS symptom score between saline only nasal irrigations versus saline nasal irrigations and nasal application of STB* wound dressing?

The primary endpoint will be the overall VAS symptom score after 6 weeks of treatment (initial treatment), comparing the two different treatments arms.

Secondary outcome

Secundary parameters:

- Comparison of nasal patency by means of NL-NOSE scale (questionnaire)

- Comparison of nasal endoscopic findings (NES score)

- Comparison of PNIF-score before and after treatment.

- Comparison of the burden of epistaxis (5-point scale).

- Comparison of the burden of nasal discharge (5-point scale).

- Difference in VAS symptom score for crust formation. (VAS)

- Difference in VAS symptom score for nasal pain. (VAS)

- Difference in VAS symptom score for loss of smell. (VAS)

Study description

Background summary

A common complaint within the ENT practice is nasal obstruction for which surgical treatment is often applied, in case conservative treatment fails.

Although there is a broad spectrum of etiologies, there is a general distinction between two categories of nasal obstruction: 1) reversible nasal obstruction, which is usually caused by inflammation of de mucosa along with secretion; 2) fixed obstruction, which is usually caused by occlusion, anatomical variation or neoplasms. One of the causes of fixed obstruction is turbinate hypertrophy, which may be sustained by inflammation caused by allergic rhinitis (AR) or non-allergic rhinitis (NAR).
The nasal turbinates are located on either site within the nose, respectively the inferior, medial and superior turbinates. The inferior turbinate alone causes about 50% of the total resistance of airflow through the nose, which means that the feeling of obstruction already occurs at minor swelling of the inferior turbinate. It is possible to evaluate subjective nasal obstruction by means of validated questionnaires and VAS. PNIF provides an objective way of measurement of airflow through the nose in which a patient is asked to inhale as powerful and quickly as possible. It is a non-invasive, cheap and easy method to use.

One of the possible ways to treat ITH is the use of ITC-RF, a method which is regularly used. ITC-RF can be performed at outpatient consultation, without major risks, by using local anesthesia. With ITC-RF the submucosal tissue of the turbinate is scarred, with the use of radiofrequent energy. This results in shrinkage of the turbinate. The radiofrequent energy is transferred by a sharp pointed probe which is brought into the turbinate. Although the invasive character of this intervention is minor, there is still an iatrogenic cause of wound formation within the nose. The cornerstone of treatment after ITC-RF consists of nasal saline irrigations. Patients are advised to irrigate the nose three times daily for six weeks.

STB* is an ointment which is based on medicinal honey. Medicinal honey has gained relative prominence over the past years within the field of wound healing. Previous research has shown that medicinal honey contains characteristics which are essential for the healing of wounds, such as suppressing long term inflammation and stimulation of anti-inflammatory cytokines. Its thick viscosity and low pH have an anti-bacterial effect and since it does not contain corticosteroids or antibiotics it is safe to use for a longer period of time

STB* nasal woundressing is well tolerated and widely used in ENT practice for the treatment of epistaxis or to diminish crusting of the nasal mucosa in for example nasal Granulomatosis with polyangiitis. Nevertheless, no studies have been performed to address it*s effectiveness in these nasal diseases.
It is available at the pharmacist and medicine specialty store with the prescription of a physician or physician-assistant. With possession of a prescription, STB* is reimbursed by the health insurance. NasuMel®, which is the same ointment as STB* wounddressing, is freely available for patients.

Study objective

In this study we will compare the therapeutic value of nasal saline irrigations only versus nasal saline irrigations combined with nasal application of STB* ointment in patients who received inferior turbinate coblation by radiofrequency (ITC-RF). We will investigate several parameters by means of a validated questionnaire (NL-NOSE scale), VAS symptom scores, endoscopic findings and an objective measurement of nasal patency by means of a Peak Nasal Inspiratory Flow (PNIF).

Study design

This study will be a single centre single-blind, randomized study in 64 subjects who have inferior turbinate hypertrophy and who have an indication for coblation treatment, who did not already receive surgical treatment for the inferior turbinate.
Subjects will be treated 3 times daily during 6 weeks with saline only- or saline nasal irrigations and nasal application of STB* ointment 3 times daily. Subjects will be randomized to saline only nasal irrigations or saline nasal irrigations and nasal application of STB* ointment.

Signs and symptoms will be measured with disease specific questionnaires. Nasal endoscopy and PNIF will give more objective information about the improvement status.

Intervention

Subjects in group 1 will be treated 3 times daily during 6 weeks with saline nasal irrigations only. Group 2 will be treated withsaline nasal irrigations and nasal application of STB* wound dressing 3 times daily.

Study burden and risks

At visit 1 the participant will fill in the NL-NOSE questionnaire (5 questions), and one other short questionnaire and perform a Peak Nasal Inspiratory Flow measurement. Every week the participant will receive a short questionnaire (maximum 5 minutes) by e-mail (6 questionnaires in total).
For 6 weeks 3 times a day one group will irrigate the nose with saline only. The other group will get this same treatment with the addition of applying STB* wound dressing in the nose.
The extent of the burden is low, because a part of the treatment is standard care.
There are no additional risks.

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

1. Subjects must have a diagnosis of bilateral inferior turbinate hypertrophy for > 6 weeks
2. Patients are capable of undergoing the coblation procedure under local anesthesia
3. Age * 18 and * 70 years.
4. Subjects must be willing to give Informed Consent and adhere to visit schedules.

Exclusion criteria

1. Subjects currently treated with anticoagulation other than thrombocyte

aggregation inhibitors.
2. The presence of nasal polyps.
3. Known systemic vasculitic and granulomatous disease.
4. Known coagulopathy.
5. Known peanut allergy.
6. AIDS or known to be HIV positive.
7. Smoking (in the past 6 months).
8. History of radiotherapy in head and neck region.
9. History of previous turbinate surgery
10. Severe anatomic abnormalities leading to an inability to administer the irrigation solution to one side of the nose.
11. Nose valve insufficiency.
12. Craniofacial malformations.
13. Abnormalities requiring other modality of therapy (obstructive polyps, tumors, infection of dental origin).
14. Subject has a psychiatric, addictive, or any disorder that compromises ability to give truly Informed Consent for participation in this study.
15. Subject may have difficulty in interpreting the questionnaires due to language or cognitive problems.
16. Patient is currently enrolled in other investigational drug trial(s) or is receiving other investigational agent(s).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-10-2019
Enrollment:	64
Type:	Actual

Ethics review

Approved WMO Date:	07-11-2019
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	09-01-2020
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NL70712.075.19

Study results

Summary results
Trial ended prematurely