Effects of STB™ wounddressing on nasal woundhealing after radiofrequency coblation treatment of the inferior turbinates

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24055

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Inferior turbinate hypertrophy

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

• Difference in mean overall nasal VAS symptom score between the two arms after 6 weeks.

Secondary outcome

• 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.
• Difference in VAS symptom score for nasal pain.
• Difference in VAS symptom score for loss of smell.

Study description

Background summary

Rationale: A common complaint within the ear, nose and throat (ENT) practice is nasal obstruction for which surgical treatment is often applied. There is a broad spectrum of etiologies of nasal obstruction, one of which is hypertrophia of the inferior turbinates. Inferior turbinate hypertrophy (ITH) is mostly treated by the use of coblation, a frequently used method in which radiofrequent energy scars the submucosa of the turbinate with shrinkage as result. Postoperatively, patients are instructed to rinse their nose with saline irrigation three times a day, for a period of 6 weeks. During this period patients can experience some minor nasal bleeding, crust formation and sometimes nasal irritation or discomfort. STB™ wounddressing (STB™) is an ointment, already regularly used in the ENT practice, based on medicinal honey that is capable of stimulating wound healing in vivo and has an antibacterial effect in vitro.
Objective: To investigate the additive effect of STB™ application to nasal saline irrigations, in patients who received inferior turbinate coblation by radiofrequency (ITC-RF).
Study design: a single-center single-blinded, randomized, study in 64 subjects with nasal obstruction who received ITC-RF.
Study population: 64 subjects with nasal obstruction based on ITH, who are referred to the outpatient clinic of Isala Klinieken.
Intervention: All subjects will be treated during 6 weeks with nasal saline irrigations with or without the addition of STB™ ointment three times daily.
Main study parameters/ endpoints: VAS symptom score, NL-NOSE scale, nasal endoscopic findings and peak nasal inspiratory flow (PNIF).

Study objective

treatment with STB wound dressing in combination with nasal saline irrigation, after coblation of the inferior turbinates, provides better wound healing compared to nasal saline irrigations only.

Study design

Once included participants will receive a questionnaire by means of e-mail once every week, for 6 weeks. Follow-up is thereby 6 weeks. After 20 weeks no more participants will be included.

Contacts

Public
Rijksuniversiteit Groningen
Tjerk Aukema

+31683210050
Scientific
Rijksuniversiteit Groningen
Tjerk Aukema

+31683210050

Eligibility criteria

Inclusion criteria

1. Subjects must have a diagnosis of bilateral ITH 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. History of radiotherapy in head and neck region.
8. History of previous turbinate surgery
9. Severe anatomic abnormalities leading to an inability to administer the irrigation solution

to one side of the nose (for example a severe septal deviation or a large bullous middle turbinate).
10. Craniofacial malformations.
11. Abnormalities requiring other modality of therapy (obstructive polyps, tumors, infection of dental origin).
12. Subject has a psychiatric, addictive, or any disorder that compromises ability to give truly Informed Consent for participation in this study.
13. Subject may have difficulty in interpreting the questionnaires due to language or cognitive problems.
14. Patient is currently enrolled in other investigational drug trial(s) or is receiving other investigational agent(s).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

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

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	02-10-2019
Application type:	First submission

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
NTR-new	NL8061
Other	METC Isala Zwolle : METC190709

Study results