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

Gepubliceerd: 02-10-2019 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24055

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Inferior turbinate hypertrophy

Ondersteuning

Primaire sponsor: Dos Medical B.V.
Overige ondersteuning: Isala Academie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Contactpersonen

Publiek

Rijksuniversiteit Groningen
Tjerk Aukema

+31683210050

Wetenschappelijk

Rijksuniversiteit Groningen
Tjerk Aukema

+31683210050

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	14-10-2019
Aantal proefpersonen:	64
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	02-10-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8061
Ander register	METC Isala Zwolle : METC190709

Resultaten