Safety and Performance of a Bioabsorbable Fluticasone Propionate-eluting sinus dressing (SinuBand) in the Postoperative management of Functional Endoscopic Sinus Surgery in patients with Chronic Rhinosinusitis

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This study is designed to evaluate the safety and performance of SinuBand, a bioresorbablefluticasone propionate-eluting sinus dressing in the postoperative management of FESS in patientswith chronic rhinosinusitis. The study will collect both…

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

Summary

ID

NL-OMON38446

Source
ToetsingOnline

Brief title
Sinuband in CRS

Condition

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

Synonym

chronic rhinosinusitis, nasal polyps

Research involving
Human

Sponsors and support

Primary sponsor: BioInspire Technologies
Source(s) of monetary or material Support: industrie

Intervention

Keyword: chronic rhinosinusitis, drug eluting dressing, nasal polyps, sinus surgery

Outcome measures

Primary outcome

Local sinus safety will be assessed by monitoring for device-related adverse

events.

Ocular safety will be characterized via baseline and follow-up (day 15 and 30)

measurement of intraocular pressure (IOP) and examination for lens opacities.

Systemic safety will be evaluated through the measure of the cortisol in 24h

urine collection at day minus 1 and at day 15.

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Secondary outcome

Reduction in ethmoid inflammation (graded in a visual analog scale 0 to 100 mm)

at any time during follow up (±2) 5, 15, 30 and 60 days) in the SinuBand FP arm

compare to the controls.

Synechiae and postoperative intervention as surgical intervention to separate

an adhesion or oral steroid intervention for recurrent ethmoid inflammation

edema and /or polyp recurrence at 30 days will also be measured.

The secondary outcome measures will be evaluated from video-endoscopies

reviewed by blinded independent panel of 3 ENT surgeons

Study description

Background summary

Chronic rhinosinusitis (CRS) is defined as an inflammation of the nose and paranasal sinuses lasting more than 12 weeks. Currently, treatment is tailored to each patient, and may be medical or surgical. Conservative treatment options include topical and courses of systemic corticosteroids, nasal irrigation with saline solution, and oral antibiotics (during flares or as long-term treatment in patients with no serum IgE elevation). Topical corticosteroids are currently the first-line drugs of choice for treatment of CRS and postoperative management of functional endoscopic sinus surgery. Their mechanism of action relies partly on their ability to reduce eosinophilic infiltration directly, but corticosteroids also act indirectly by reducing cytokine release by the nasal mucosa and epithelial cells present in nasal polyps. However, the distribution of CS after topical administration via nasal spray is highly variable. It is believed that delivery of CS to the ethmoid sinus cavity can still be optimized, which would improve localized drug performance.In cases refractory to medical treatment, functional endoscopic sinus surgery is indicated.
Surgical treatment may fail due to a variety of reasons, including formation of synechiae, recurrence of nasal polyps, mucosal inflammation, lateralization of the middle turbinate and ostial stenosis of the operated sinus.Topical nasal CS therapy after surgical treatment is an established strategy for ensuring more effective and long-lasting symptomatic benefit, as well as reducing polyp size and number and preventing polyp recurrence.Within this context, there has been growing interest in the use of bioabsorbable materials such as SupraGel*, Surgicel®, and
carboxymethyl cellulose derivatives in the middle meatus in an attempt to optimize postoperative outcomes and decrease the incidence of epistaxis. Doubts remain as to whether these materials can decrease the risk of synechiae, potentiate the use of topical drugs in the postoperative period, or prevent polyp recurrence.
In this regard, some studies have reported benefit with the use of absorbable CS-eluting patches and stents in the ethmoid sinus cavity, by reducing postoperative adhesions, crusting, discomfort and, particularly, local inflammation.
The use of an absorbable drug-eluting stent containing a topical CS, mometasone furoate, in a rabbit model, confirmed the local steroid delivery with minimal systemic absorption. The followed human study, Advance II, of this product has

demonstrated that the stent has significantly reduced post-operative interventions by 29% with minimal local and systemic adverse effects. Placement of a slow-release fluticasone propionate dressing in the ethmoid sinus cavity after ethmoidectomy may, by reducing inflammation, minimize the aforementioned postoperative complications, improving the success rate of surgery.

Study objective

This study is designed to evaluate the safety and performance of SinuBand, a bioresorbable
fluticasone propionate-eluting sinus dressing in the postoperative management of FESS in patients
with chronic rhinosinusitis. The study will collect both qualitative and quantitative data recorded by
the investigators during the procedure to determine safety and efficacy of the device.
2.1.1 Primary Objective:
The primary objective of this trial is to evaluate the safety of the investigational product
in patient with chronic sinusitis undergoing FESS.
2.1.2 Secondary Objective:
The secondary objective is to assess the performance of SinuBand in the improvement of
clinical and endoscopic parameters in patients with chronic rhinosinusitis following FESS.

Study design

Randomized, partialy double-blind, single center, controlled clinical trial. Patients shall be used as their own controls, with implantation in each ethmoid sinus with one of the three options: Sinuband with the FP, SinuBand without FP (the study will be double blind on the presence of the FP) or regular care with *Merocel* pack At the end of the intervention a block randomization will establish which side will receive which treatment. The follow-up period is designed to assess the safety and efficacy of the fluticasone propionate-eluting sinus dressing.

Intervention

At the end of the endonasal portion of the FESS procedure the operating surgeon shall place either SinuBand with FP, Sinuband without FP or regular *Merocel* pack. Randomization by block of 6 will determine which treatment option to be applied to each of the new ethmoid cavities.
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Study burden and risks

Time: around 3 hours extra time of the patients divided into 5 visits
Three times: ophtalmologic examination
Twice: collection of urine during 24 hours.
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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

Patients aged >18 years, with chronic rhinosinusitis (with nasal polyps), in whom bilateral endoscopic endonasal anterior and posterior ethmoidectomy is indicated due to failure of medical treatment, whether as first surgical approach or as revision surgery.

Exclusion criteria

Patients with a known history of corticosteroid (CS) intolerance will be excluded from the study, as well as those dependent on oral CS or with a history of immunodeficiency, fungal rhinosinusitis, previous nasal polyp surgery in which the middle turbinates have been removed on one or both sides, severe asthma, glaucoma, cataract, or insulin-dependent diabetes mellitus. Patients with known hypersensitivity to any component of SinuBand will be excluded from the study

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-07-2013
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	sinus dressing
Registration:	No

Ethics review

Approved WMO Date:	08-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL43342.018.13