The effect of duration of nonabsorbable nasal packing (merocel) soaked with oxytetracycline and hydrocortisone (terrracortril) in the post-operative management of functional endoscopic sinus surgery in patients with chronic rhinosinusitis with nasal polyps (CRSwNP) on healing of the sinus cavity

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON42966

Source
ToetsingOnline

Brief title
The effect of nasal packing in the post-operative management of FESS

Condition

- Respiratory tract therapeutic procedures

Synonym
nasal polyps, sinus inflammation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chronic rhinosinusitis, endoscopic sinus surgery, postoperative management

Outcome measures

Primary outcome

Ethmoid inflammation

Mean difference in ethmoid inflammation and polyp score (graded in a visual

analog scale 0 to 100 mm) between two sides on day 30 (± 7 days).

Secondary outcome

Mean difference in ethmoid inflammation (graded in a visual analog scale 0 to

100 mm) between two sides. This will be assessed during two follow up visits:

day 90 (± 14 days) and day 180 (± 14 days).

Polyp score

Mean difference in the polyp score between two sides. It will be assessed three

times during follow up: day 30 (± 7 days), day 90 (± 14 days) and day 180 (± 14

days).

Presence of synechiae:

Mean difference in synechiae presence (graded in a visual analog scale 0 to 100

mm) between two sides. The presence of synechiae will be assessed on three

different follow up visits: day 30 (± 7 days), day 90 (± 14 days) and 180 (± 14 days).

Middle turbinate position:

Mean difference in middle turbinate position (lateralized, medialized or neutral) between two sides will be assessed on three different follow up visits: on day 30 (± 7 days), 90 (± 14 days) and day 180 (± 14 days).

Modified Lund-Kennedy score:

Mean difference in the modified Lund-Kennedy score between two sides. The modified Lund Kennedy score will be assessed three times during follow up: day 30 (± 7 days), day 90 (± 14 days) and day 180 (± 14 days).

Patient discomfort

Mean difference of overall patient`s discomfort score determined by severity of nasal symptoms (graded 0-5) between two sides. Patients will be given a diary, and asked to assess their discomfort daily.

Three ENT surgeons will independently assess the ethmoid inflammation, presence of synechiae, position of middle turbinate and the modified Lund-Kennedy score system through blinded video-review.

Study description

Background summary

Chronic rhinosinusitis is a very prevalent condition which affects approximately 14% of the Dutch general population [1]. Distinction is made

between, chronic rhinosinusitis without nasal polyps and chronic rhinosinusitis with nasal polyps (CRSwNP). CRSwNP in adults is defined as presence of two or more symptoms, one of which should be either nasal obstruction / blockage / congestion or nasal discharge / postnasal drip, and can be accompanied with facial pain, pressure and reduction or loss of smell lasting for at least 12 weeks. Nasal polyps must be visualized bilaterally on the endoscopical examination in the middle meatus [2]. Treatment of CRSwNP should be tailored to each patient, and may be conservative or surgical. Conservative treatment options include topical steroids, nasal irrigation with saline solution, and oral antibiotics. If conservative management fails to improve symptoms, surgical treatment should be considered [2]. However, the optimal surgical treatment for CRSwNP has yet to be identified.

Functional endoscopic sinus surgery (FESS) is considered a safe and effective treatment (EPOS) and is commonly performed in the Academic Medical Center (AMC). The underlying principle of FESS is the restoration of the anatomy and function of the respiratory epithelium of the paranasal sinuses in minimally invasive fashion [3][4]. Even after a successful surgery, surgical treatment may fail due to a variety of reasons which can occur postoperatively, including mucosal inflammation, lateralization of the middle turbinate, formation of synechiae, recurrence of nasal polyps and ostial stenosis of the operated sinus [5][6][7][2]. To prevent the occurrence of these changes and optimize treatment outcome, several postoperative management strategies have been developed. These postoperative management strategies often include the local administration of corticosteroids in the sinus cavity to reduce mucosal inflammation and stabilization of the medialized turbinate.

Up to date, there is no consensus on the optimal postoperative management of FESS in patients with CRSwNP. Consequently, there are several techniques in use, such as; the placement of nonabsorbable nasal packing with or without local corticosteroid [8][9][10][11], drug eluting absorbable stents [12][9], microde-brider medialization technique [13], and middle turbinate suture technique [14]. Moreover, there are also authors who prefer no placement of the nasal packing [15][9].

Study objective

The primary objective is to assess whether a 10-14 day Merocel with TC packing of the sinus is better than a one day Merocel with TC packing in the improvement of clinical and sinus parameters in patients with symmetrical CRSwNP following FESS. The 0 hypothesis is that there is no difference in inflammation between one day packing or 10-14 days packing of the sinus with Merocel with TC. The secondary objective of this trial is to evaluate the level of improvement in nasal symptoms, for which the patient*s subjective discomfort level will be scored.

Study design

This randomized, single center, controlled clinical trial shall be conducted at the Academic Medical Center (AMC), Department of Otorhinolaryngology. The sample size will consist of 20 patients having FESS due to CRSwNP refractory to medical treatment. This study is designed to evaluate whether a 10-14 day Merocel with TC packing of the sinus is better than a one day Merocel with TC packing. Patients will be used as their own controls, with packing duration randomized per side (ethmoid).

Intervention

At the time of the procedure, the packing will be prepared for use according to its *Directions for Use*. Patients will be prepared in the normal manner for endonasal surgery. Intravenous CS shall be administered during anesthetic induction. Antibiotic therapy shall consist of cefazoline 1000mg, during the anesthetic induction and amoxicillin/clavulanate 625mg per os every 8 hours for 14 days after surgery. Patients with penicillin allergy shall receive levofloxacin 500 mg once daily or clindamycin 300mg three times daily instead.

At the end of the procedure and in absence of complication, the operating surgeon shall receive two Merocel packings with TC which will be inserted to the nasal cavity as per "Directions for Use". To prevent introduction of confounding factors, no other hemostatic materials shall be allowed in any of the ethmoid cavities. Packing of the inferior meatus shall be allowed only if necessary and as long as it remains inferior to the middle meatus. If excessive bleeding requires further hemostatic material the patient shall be excluded. Surgical manipulation of the middle turbinate for medialization or partial resection will be allowed. Complete surgical removal of middle turbinate will not be allowed. All procedures shall be recorded onto physical media and reviewed to ensure uniform compliance with all study specifications. Topical CS will be started one day after packing removal.
At the end of the procedure, the randomization process will assign a number for each packed side separately.
Directions for Use
* Inspect the package for any obvious damage, discard if damaged.
* Open the package through the tear-notch.
* Open the foil packaging.
* Inspect the Merocel packing. If the Merocel packing is broken or damaged discard and obtain a new Merocel packing.
* Open the package using sterile technique.
* Using a carefully dried *pick up* or forceps hold Merocel packing by one extremity.
* Smear the TC ointment over the surface of the Merocel packing.
* Remove excessive TC ointment.
* Ensure hemostasis in operated sinus cavities prior to insertion.

* Gently introduce the Merocel with TC packing into the nasal cavity.
* Under endoscopy apply it into the surgically treated ethmoid sinus.
* Make sure all parts of the device are well apposed against the tissue.
* Confirm final placement by endoscopic visualization.

Study burden and risks

Terracortril and Merocel are registered products.
The use of nasal packing with Merocel and Terracortril may carry the following risks:
Mild risks: discomfort and irritation.
Moderate risks: headache, hypersensitivity, bronchospasm, pack dislodgement, foreign body granuloma and bleeding after removal.
Severe: status asthmaticus, angioedema, anaphylactic shock, blood dyscrasias, convulsion, aspiration and toxic shock syndrome

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, symmetrical crswnp, in whom bilateral primary or revision endoscopic ethmoidectomy is performed due to failure of medical treatment. Intervention on other paranasal sinuses (with the exception of extensive frontal sinus intervention (Draf 3) and correction of septal deviation as part of the study procedure shall be allowed when necessary

Exclusion criteria

Patients dependent on oral CS and patients who took oral CS from 30 days before the surgery. Patients with cystic fibrosis, antrochoanal polyp, inverted papilloma and vasculitis. Patients with known hypersensitivity to any component of Terracortril will be excluded from the study.

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):	07-11-2016
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Merocel and terracortril
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-11-2016
Application type:	First submission
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	NL59079.018.16