Closure of oroantral communications using biodegradable polyurethane foam; a prospective clinical trial

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Goal of this study is to assess the treatment of OACs with biodegradable polyurethane foam, as carried out in the pilot studies, in a large number of patients.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Head and neck therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON33141

Source
ToetsingOnline

Brief title
The "RAPID" study III

Condition

- Head and neck therapeutic procedures

Synonym
oroantral communication (OAC), oroantral fistula/perforation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: biodegradable, foam, oroantral communication, polyurethane

Outcome measures

Primary outcome

Primary endpoint of the study is the technical success of each treatment, defined as the successful application of the PU foam, without recurrence of the perforation. The oral mucosal overgrowth mucosa will be examined to evaluate this endpoint and the patient will be asked to gently blow his/her nose to make sure no air can pass through the perforation.

Secondary outcome

The VAS-pain score will be documented in every visit. Also, patient satisfaction and complications like maxillary sinusitis and complicated wound healing will be documented.

Study description

Background summary

An oroantral communication (OAC) is an open connection between the oral and paranasal cavity. In general, an OAC is caused by extraction of maxillary (pre)molars. Although the incidence is relatively low, OACs are frequently encountered due to the high number of dental extractions. To minimize the risk of chronic sinusitis and the development of fistulas, it is generally accepted that all OACs should preferably be closed within 24 hours. Surgical closure with a mucoperiosteal flap is the treatment of choice nowadays. The patient has to be referred to a maxillofacial surgeon for this treatment, because in general the dentist does not have the expertise and the facilities to treat an OAC himself.
Another major objective of the surgical treatment for edentulous patients is the fact that the buccal sulcus depth almost certainly decreases permanently after closure with a buccal flap, thereby hindering the fitting of a well-fitted dental prosthesis.

The proposed treatment with a biodegradable polyurethane foam meets this objections because it is a quick, safe and simple strategy and does not require additional surgical skills. This will make it possible for a dentist to treat an OAC himself, instead of having to refer the patient to the maxillofacial surgeon. Furthermore, the proposed treatment has no influence on the buccal sulcus depth. In addition, the PU treatment gives rise to less postoperative pain and swelling. Lastly, due to the biodegradability of the foam, a second visit for removal of the foam is not necessary

Study objective

Goal of this study is to assess the treatment of OACs with biodegradable polyurethane foam, as carried out in the pilot studies, in a large number of patients.

Study design

The study is a supplemental study to the previous pilot studies. In the second pilot study the PU treatment and its protocol were perfectioned. In the current study the treatment will be evaluated on a larger scale. A group of maximally 108 patients with fresh OACs will be treated with PU foam. A stopping rule will monitor the ending of the study in case the results are either more positive or more negative than anticipated. Based on a study on the complication ratio after surgical closure of OACs, and the results of both pilot studies, it is expected that the number of recurrences of OACs will be between 5 % and 12,5 %. The data will be analysed sequentially to minimize the need of included patients in order to gain statistically significant results.
Each patient with a oroantral communication on the outpatient department of oral and maxillofacial surgery will be evaulated on the inclusion criteria.
Next, each selected patient will be treated with PU foam until statistically significant results are obtained.

Intervention

All included patients will be treated in the same manner. The size of the oroantral communication will be examined and a polyurethane foam is selected that matches its size. Secondly a safety-suture is attached to the PU foam to facilitate removal of the foam in case it is accidentally pushed through the perforation into the maxillary sinus. Hereafter, the foam is fitted in the perforation and the safety suture is removed. Lastly, the PU foam is loosely secured on the oral side with a suture to ensure the PU foam stays in place.

Study burden and risks

To our point of view the proposed treatment implies both a minimal risk and burden for the patients involved in the study. Firstly, the treatment is

quicker than the conventional surgical treatment. Secondly, the swelling and postoperative pain are less prominent after closure with PU foam. Furthermore, the most important risk associated with participation in the study is possible recurrence of the OAC. However, in such cases, the attending physician can always fall back on the conventional surgical treatment. Laslty, the number of policlinical visits asscociated with participation in the study is restricted to 3 visits, which is only slightly more than usual (2 visits)

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
postbus 30 001, 9700 RB Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
postbus 30 001, 9700 RB Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Male or female aged 18 years or older.
2.The patient requires a (surgical) treatment for an oroantral communication.
3.The period between occurrence of the oroantral communication and treatment is less than

24 hours.
4.The patient is willing and able to comply with the specified follow-up evaluation.
5.The patient or legally authorized representative must provide written informed consent prior to the procedure

Exclusion criteria

1. Patients who require endocarditis prophylaxis or antibiotic prophylaxis for other indications.
2. Patients associated with infections at the time of intervention.
3. The period between occurrence of the oroantral communication and treatment is more than 24 hours.
4. Patients with a history of past or present immunosuppressive condition, either due to a disease or immunosuppressive medication.
5. Inflammation at the site of the antral perforation.
6. Patients enrolled in this or other clinical trial or anticipated to be included into a trial, which may interfere with this study.
7. Patients with acute or chronic maxillary sinusitis.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2009
Enrollment:	108
Type:	Actual

Medical products/devices used

Generic name:	biodegradable polyurethane foam
Registration:	No

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL28924.042.09