# Closure of oroantral communications using a biodegradable polyurethane foam;
# a refined procedure

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Head and neck therapeutic procedures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON32148

**Source**
ToetsingOnline

**Brief title**
The *RAPID* Study II

### 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

The primary endpoint is the technical success, defined as the successful application of the polyurethane foam, without reoccurence of a perforation secondary to loss of the foam or inadequate fitting. The oral mucosal overgrowth will be examined to evaluate these endpoints.

Safety parameters: the safety outcome of the study will be described in terms of the incidence of procedure or device related adverse events occuring up to and including 8 weeks after application in the oroantral perforation.

### Secondary outcome

patient friendliness and device appreciation (physician)

# Study description

### Background summary

An oroantral communication (OAC) is a communication between the oral and nasal cavity. In general, an OAC is caused by extraction of maxillary (pre)molars. Although the incidence is relatively low (5 %), OACs are frequently encountered due to the high number of extractions.
To prevent chronic sinusitis and the developmentment of fistulas, it is generally accepted that all OACs should be closed within 24 to 48 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 surgical treatment because, in general, the dentist does not have the expertise and the required facilities to treat the OAC himself.

Another major objective of the surgical treatment for edentulous patients is the fact that the buccal sulcus height almost certainly decreases permanently, thereby hindering the construction 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 expertise. This will make it possible for a dentist to treat an OAC himself instead of having to refer the patient to a specialist. Furthermore, the proposed strategy has no influence on the buccal sulcus height.
In addition, it is expected that, compared with the conventional surgical treatment, the proposed strategy will result in less postoperative pain and swelling. Lastly, due to the biodegradability of the polyurethane foam, a second visit for removal of the foam is not necessary.

## Study objective

Goal of this study is to assess the feasibility of a biodegradable polyurethane foam for closing of oroantral communications with a few modifications compared to the first pilot study. The assessment will take place in a small number of patients. On the long term, the objective is the clinical appliance of the polyurethane foam on a large scale.

## Study design

This single center study represents the pilot phase of the study design. During the pilot phase, the feasibility of the proposed treatment will be assessed in 10 patients. During the pilot phase every patient with an OAC at the department of oral and maxillofacial surgery of the UMCG will be examined and included in the study when the inclusion criteria are met. Secondly, all selected patients with an OAC will be treated with the polyurethane foam until a total number of 10 patients is reached. A prospective multi center trial will be set up when the pilot phase has been finished

## Intervention

All patients (n = 10) 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 suture is attached to the foam to enable removal of the foam in case it is pushed through the perforation. Hereafter, the foam is fitted in the perforation and loosely secured on the oral side with one 3.0 or 4.0 vicryl suture to ensure that the foam stays in place.

## Study burden and risks

To our point of view the proposed strategy implies both a minimal risk and burden for the patients. Firstly, it is expected that the proposed treatment is

quicker than the conventional surgical treatment. Secondly, the swelling and postoperative pain will most likely be less prominent after the proposed treatment. Furthermore, the most important risk associated with participation is possible reoccurence of an OAC, for example due to loss of the foam. However, in case an OAC reoccurs, the attending physician can fall back on the conventional surgical strategy in any case. Lastly, the number of policlinical visits associated with participation in this study has been restricted to a total of 3, which is only slightly more than general (2 visits).

## 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

Fresh oroantral communication (existing less than 24 hours)

### Exclusion criteria

Oroantral communication existing for more than 24 hours.
Patients who require endocarditisprophylaxis or antobiotic prophylaxis for other indications.
A history of acute or chronic sinusitis.
Immune compromised patients.

## Study design

### Design

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| Study phase: | 2 |
| Study type: | Interventional |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-06-2008 |
| Enrollment: | 10 |
| Type: | Anticipated |

### Medical products/devices used

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|---|---|
| Generic name: | biodegradable polyurethane foam |
| Registration: | No |

## Ethics review

Approved WMO

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| 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 | NL23138.042.08 |