Biodegradable polyurethane foam modified with 55% polyethyleneglycol as a local hemostatic agent, a pilot study.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31951

Source
ToetsingOnline

Brief title
Polyurethane foam as a local hemostatic agent.

Condition

- Other condition
- Head and neck therapeutic procedures

Synonym
coagulation

Health condition

Stolling van humaan bloed

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: Coagulation, Extraction, Local hemostatic agent, Polyurethane

Outcome measures

Primary outcome

The primary study parameter is the degree of clotformation (concentration

thrombin) in polyurethane foam in comparison with the baseline values of the

blood and the concentration thrombin in Willospon and Novacol.

Secondary outcome

Not applicable

Study description

Background summary

Like in any kind of surgery, extraction of teeth can result in (postoperative) bleeding. Such bleeding can be treated by means of a local hemostatic agent. Patients who use oral anticoagulant therapy require to stop the anticoagulant therapy prior to surgery to prevent postoperative bleeding after tooth extractions. However, ceasing the use of these drugs increases the risk of thromboembolic events. With the use of local hemostatic agents after dental extractions to control local bleeding, the risk of such thromboembolic events could be diminished.
In dentistry, local hemostatic agents are already used for application in sockets after extraction. Until now, these local hemostatic agents are of animal derived origin. Transmission of pathogens might be a possible complication of these products. Therefore, attention is currently focused on local hemostatic agents that are fully synthetic. It is anticipated that these synthetic foams can be used in all patients, including patients on anticoagulant therapy.
Polyurethane foam modified with 55% polyethyleneglycol is a fully synthetic

foam, and it has proven to be both biodegradable and biocompatible.

Study objective

Goal of this study is to asses the feasibility of polyurethane foam as a local hemostatic agents in sockets after dental extraction. The assessment will take place in a small number of patients.
After the pilot study, a large study will be implemented to evaluate the polyurethane foam as a local hemostatic agent in all patients, including patients on anticoagulant therapy.
On the long term, the objective of the study is the clinical appliance of polyurethane foam as a local hemostatic agent in all patients.

Study design

This splitmouth experiment represents the pilot phase of the study design. During the pilot phase, the feasibility of polyurethane foam modified with 55% PEG as a local hemostatic agent wil be examined in 10 patients. During the pilot phase, each patient who requires at least 2 extractions in 1 session will be examined and included in the study when all inclusion criteria are met. Secondly, all selected patients will be treated by means of the protocol until a total number of 10 patients is reached.

Intervention

The selected patients will be divided into two groups. In the first group the degree of clotformation in polyurethane foam will be compared to the degree of clotformation in Willospon (absorbable gelatine sponge; Will-Pharma BV, Zwanenburg, Nederland). In the second group the degree of clotformation in polyurethane foam will be compared to the degree of clotformation in Novacol (absorbable collagen hemostat; Bioprof BV, Moerkapelle, Nederland). Novacol and Willospon are already used as local hemostatic agents in the dentistry. Only 1 kind of foam will be tested in each socket.

Study burden and risks

To our point of view the proposed stategy implies both a minimal risk and burden for the patients. Firstly, the time needed for the treatment will not take longer than the original treatment. Secondly, the foams are removed in the same session. Participation in this study does not have consequences for the number of policlinical 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

patients who require at least 2 extractions in 1 session

Exclusion criteria

Patients under 18 years and immune compromised patients.
Patients who use oral anticoagulant therapy.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	20-04-2008
Enrollment:	10
Type:	Anticipated

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	NL22629.042.08