The effect of continuation of anti-platelet agents on bleeding complications after dento-alveolar surgical procedures.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22690

Source
NTR

Brief title
BLACK

Health condition

caries, parodontitis apicalis, adult parodon titis

Sponsors and support

Primary sponsor: Academic Medical Center, department of Oral Maxillofacial Surgery, Academic Medical Center, department of Internal Medicine
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

The primary outcome of the study is peri-procedural blood loss.

Secondary outcome

Secondary outcome is the occurrence of thrombo-embolic events at 30 days follow-up. The predictive effect of measurements in DNA, blood and saliva on peri-procedural hemostasis and blood loss is also a secondary endpoint.

Study description

Background summary

Summary of the Study:

RESEARCH QUESTIONS:

1. Is there significant more bleeding or blood loss in patients who continue antiplatelet medication during oral surgery during and after the procedure?

2. Are local hemostatic measures sufficient to control any intraoperative or postoperative bleeding in patients that have continued antiplatelet treatment?

Study procedure:

All standard precautions to protect the patients' privacy will be taken, including coding of the results. The patient will be seen at intake, the day of surgery and at one day and 10 days post-surgery. At the day of intake and the day of surgery blood and saliva samples will be collected. Patients will be randomized to continue their medication or stop treatment. The study will be double blind; Hence, patients will receive their initial medication in the form of study medication or placebo in the form of study medication for ten days prior to their treatment.

Patients will be treated according to the usual treatment protocol. One day after surgery patients continue their medication as they used before their participation in this research. Follow-up is performed at 1 and 10 days after surgery (visit to the clinic) and at 30 days after the procedure by telephone.

Outcome and measurements:

The primary outcome of the study is peri-procedural blood loss. Secondary outcome is the occurrence of thrombo-embolic events at 30 days follow-up. The predictive effect of

measurements in DNA, blood and saliva on peri-procedural hemostasis and blood loss is also a secondary endpoint.Assessment of peri-operative bleeding will be performed by two clinicians. Intraoperative bleeding is measured by subtracting the volume of irrigation fluid from the blood accumulated in the suction trap. Postoperative bleeding is measured by measuring the blood accumulated in the suction trap. The number of patients that continue to bleed after 15 and 30 minutes will be recorded. If patients have ongoing bleeding at 30 minutes after the treatment they will be treated with standard pro-hemostatic interventions by consultation with the department of Internal Medicine (Hemostasis consultant). 30 days after the surgery the patient will be asked to answer some questions by telephone concerning thrombo-embolic events during the 30-day period after surgery. Thrombo-embolic events that are reported by patients will be verified by medical records, admission charts, investigations performed, etc.

Benefits:

Patients may benefit directly from this study, since discontinuation of antiplatelet therapy itself may result in embolic events but on the other hand may be unnecessary, which will theoretically lower their risk of thromboembolism. The results of the study will lead to a better understanding of the effect of the differences of continuation and discontinuation of antiplatelet therapy on intraoperative and postoperative bleeding after dentoalveolar surgical procedures. At termination of the study and analysis of the data a protocol will be presented to general practitioners, dentists, oral maxillofacial surgeons and internal medicine colleagues on the scientific guidelines for patients on antiplatelet therapy needing or undergoing dentoalveolar surgical procedures.

Study objective

Common traditional practice until now has been discontinuation of the antiplatelet therapy 7 to 10 days prior to dental surgery, but controlled prospective data in the literature to support this practice are lacking. The discontinuation of antiplatelet treatment to ensure an adequate hemostasis during and after dental surgery needs to be offset against the (rebound) risk of thrombo-embolic complications if this treatment is stopped.

The hypothesis is that antiplatelet therapy can safely be continued prior to dental surgery.

Study design

N/A

Intervention

Continuation of anti-platelet agents during the ten days prior to the procedure.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patient on antiplatelet therapy who has to be treated in the AMC at the Department of Oral and Maxillofacial surgery;

2. Approval of the prescribing physician;

3. At least 18 years old.

Exclusion criteria

1. Known coagulation defect;

2. Use of oral anticoagulant treatment (vitamin K antagonists) or therapeutic heparin;

3. Severe kidney dysfunction (creatinin clearance < 20 ml/min) or hepatic dysfunction;

4. Unstable coronary artery disease;

5. Patients younger than 18 years of age;

6. Refusal to provide informed consent;

7. Recent placement of a coronary stent (during the last 6 month).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2005
Enrollment:	145
Type:	Actual

Ethics review

Positive opinion

Date:	07-02-2006
Application type:	First submission

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
NTR-new	NL544
NTR-old	NTR599
Other	: N/A
ISRCTN	ISRCTN54741248

Study results

Summary results
N/A