

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

Submission date 08/03/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/03/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/08/2009	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Acronym

BLACK

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Randomised double blind placebo controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Parodontitis apicalis, adult parodontitis, caries

Interventions

Patients will be randomised to continue their medication of anti-platelet agents during the ten days prior to the procedure or to 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.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Peri-procedural blood loss

Key secondary outcome(s)

1. Occurrence of thrombo-embolic events at 30 days follow-up
2. The predictive effect of measurements in DNA, blood and saliva on peri-procedural hemostasis and blood loss

Completion date

01/09/2007

Eligibility

Key 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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Known coagulation defect
2. Use of oral anticoagulant treatment (vitamin K antagonists) or therapeutic heparin
3. Severe kidney dysfunction (creatinine 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 months)

Date of first enrolment

01/09/2005

Date of final enrolment

01/09/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Center (AMC)

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Centre (AMC) (Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Center (AMC) Department of Oral- and Maxillofacial Surgery and Department of Internal Medicine (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration