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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/03/2006	**Overall study status** Completed	
Last Edited 19/08/2009	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Peri-procedural blood loss

Secondary outcome measures
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

Overall study start date
01/09/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
145

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)

Sponsor details
Department of Oral and Maxillofacial Surgery
P.O. Box 22660
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1100 DD

Sponsor type
Not defined

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration