

Dental implant surgery for patients on oral anticoagulants

Submission date 02/03/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 17/03/2009	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 17/03/2009	Condition category Oral Health	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
006

Study information

Scientific Title
Flapless dental implant surgery for patients on oral anticoagulants: a novel bridging paradigm between clinical technique and therapeutic guidelines (WarLess Procedure)

Study objectives

To evaluate the combination of minimally invasive flapless dental implant surgery without interrupting the regular dose of the anticoagulant medications.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research and Ethics Committee, Sultan Bin Abdulaziz Humanitarian City gave approval on the 23rd March 2007 (ref: 006)

Primary study design

Observational

Study design

Observational cohort case study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Haematology/dental implants

Interventions

Males and females with a history of rheumatic heart disease were included for the case study. Four tablets of amoxicillin 500 mg (2 grams) were given to both patients one hour pre-operatively as a prophylactic antibiotic. Patients were instructed to rinse their mouth for 30 seconds with mouth rinse (chlorhexidine) prior to the dental surgery. Infiltration of one carpule of local anaesthesia (2% lidocaine with 1:100,000 epinephrine) was administered around the edentulous area and then the flapless dental implant procedure was performed. Radiographic images were taken pre- and post-implant insertion. Patients were given post-operative instructions and the antibiotic was prescribed (amoxicillin 500 mg, three times/day) for the next ten days with analgesics (ibuprofen 400 mg) to be taken only in need.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Amoxicillin, chlorhexidine, lidocaine, epinephrine, ibuprofen

Primary outcome(s)

1. Bone healing
2. No bleeding

Measured at baseline, 1-week, 4-week and 6-month follow-up visit.

Key secondary outcome(s)

No secondary outcome measures

Completion date

29/09/2008

Eligibility

Key inclusion criteria

1. History of rheumatic heart disease
2. Long term anticoagulant maintenance therapy with warfarin
3. Missing tooth/teeth
4. Both sexes, aged from 40 to 60 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. International normalised ratio (INR) greater than 4.1
2. No missing tooth/teeth

Date of first enrolment

06/04/2007

Date of final enrolment

29/09/2008

Locations

Countries of recruitment

Saudi Arabia

Study participating centre

Sultan Bin Abdulaziz Humanitarian City

Riyadh

Saudi Arabia

11536

Sponsor information

Organisation

King Abdulaziz City for Science and Technology (Saudi Arabia)

ROR

<https://ror.org/05tdz6m39>

Funder(s)**Funder type**

Research organisation

Funder Name

King Abdulaziz City for Science and Technology (Saudi Arabia) - General Directorate of Research Grants Programmes

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration