Dental implant surgery for patients on oral anticoagulants

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Hamad Al Zoman

Contact details

Sultan Bin Abdulaziz Humanitarian City P.O. Box 64399 Riyadh Saudi Arabia 11536

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)

Study design

Observational cohort case study

Primary study design

Observational

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 preoperatively 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 peformed. 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

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes