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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

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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)

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 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 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