

Dental implant surgery for patients on oral anticoagulants

Submission date 02/03/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/03/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/03/2009	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

1. Bone healing
2. No bleeding

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

Secondary outcome measures

No secondary outcome measures

Overall study start date

06/04/2007

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

Age group

Adult

Sex

Both

Target number of participants

2

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)

Sponsor details

General Directorate of Research Grants Programmes

P.O Box 6086

Riyadh

Saudi Arabia

11442

Sponsor type

Government

Website

<http://www.kacst.edu.sa>

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

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