

# Dental implant surgery for patients on oral anticoagulants

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