ISRCTN33469250 https://doi.org/10.1186/ISRCTN33469250

Implant stability in the posterior maxilla: a controlled clinical trial

Submission date
09/04/2017

Recruitment status
No longer recruiting

Registration date
22/04/2017

Overall study status
Completed

Last Edited
22/06/2017

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dental implants are artificial roots (usually titanium screws) which are screwed into the jaw bone to support one or more false teeth. They are considered to be the best treatment option to replace lost teeth or those so damaged that they cannot be repaired. In order for this treatment to be successful however, a certain amount of bone is needed to replace lost teeth with dental implants. This can present a challenge in patients who have bone loss. Dental techniques that initiate new bone growth are therefore important. A new type of surgery called maxillary sinus augmentation (regeneration) can help the body to regenerate bone where it was lost so that dental implants can be anchored; alternatively, bone can be taken from elsewhere and used in place of the lost bone (bone graft). The stability of implants is important to ensure that they last. The aim of this study is to look at the stability of implants in patients who have implants fitted alone and with regeneration or bone grafts.

Who can participate?
Healthy adults who need one or more dental implants fitted

What does the study involve?
Participants are divided into one or more of the three study groups with different grades of bone regeneration needed to anchor implants. One patient may be in several groups for different areas of their mouth. Those in the first group have implants without the need for regeneration, those in the second group have a small bone graft when their implants are put in place, and those in the third group have regenration in order to place their implants. Participants in this third group need to wait 8-10 months for healing before the implants can be placed. In each group, at the time the implants are placed and then 15, 30, 45 and 60 days later, they undergo a dental examination to assess the stability of their implants.

What are the possible benefits and risks of participating?
Participants benefit from receiving dental implants which will help to restore function. There are no notable risks involved with participating other than the general risks involved with having dental implants fitted.

Where is the study run from?
Clinica Médico-Dentária RZG (Portugal)

When is the study starting and how long is it expected to run for?
September 2013 to July 2016

Who is funding the study?
University of Porto (Portugal)

Who is the main contact?
Dr Raquel Zita Gomes
mvasconcelos@fmd.up.pt

Contact information

Type(s)
Scientific

Contact name
Dr Raquel Zita Gomes

ORCID ID
http://orcid.org/0000-0002-3360-3903

Contact details
Faculty of Dental Medicine, University of Oporto (FMDUP)
Rua Manuel Pereira da Silva, 392
Oporto
Portugal
3850-127
+351 (0)962 647 008
mvasconcelos@fmd.up.pt

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
University of Oporto Trial Number #890573

Study information

Scientific Title
Controlled clinical trial about the effects of bone regeneration in the implant stability during the healing phase

Acronym
ISPM

Study objectives
The aim of this study is to evaluate the stability of dental implants at placement in the human posterior maxilla and to investigate the evolution from primary to secondary stability, in three different groups: patients with native bone, patients with partially regenerated bone and patients with nearly totally regenerated bone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Faculty of Dental Medicine of the University of Oporto, 26/06/2014, ref: #890573

Study design
Interventional prospective non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Implant dentistry

Interventions
Following provision of informed consent, eligible participants are allocated into one (or more) of three study groups depending on the levels of osseous-regeneration needed in Superior Posterior (SP) area of the maxilla. Implants in the same patient can be of different groups and are always considered as independent. Dental implants placed in different situations of bone regeneration (none, partial, almost total) are therefore examined in this study rather than individual patients. So one patient can be allocated in different groups because he could have different implants placed in different regeneration situations.

Group 1: Patients have a posterior non-regenerated (NR) maxillary bone (healed site) that needs one or more implants. The intervention in this group is the implant placement only (patients received one or more dental implants) with no regeneration prior or concomitant.

Group 2: Patients have a posterior partially regenerated (PR) maxillary bone at the time of implant placement. The interventions on this group is the implant placement and the simultaneous bone regeneration in cases of small bone defects or post extractional implants. The bone graft is done at the surgery of the implant placement.

Group 3: Patients have the necessity of major regeneration with a sinus lift and filling (almost nearly total regenerated (TR) site) healed in the posterior maxilla to permit the implant placement. So the interventions in this group are the bone regeneration of the maxillary sinus (sinus lift and filling) and the implant placement after the healing of the bone graft on the sinus (8 to 10 months).

The study is performed over a period of one year and three months. The cases with sinus lift and filling had at least 8 to 10 months of healing prior to the implant placement. For those in group 3 there is a longer follow up period, because the monitoring is from the bone graft (healing controlled clinically and by X-ray every 3 months) on the sinus until the follow up after the implant placement.

The follow-up after implant placement is the same in the three groups and lasts at least of 2 months but, in critical conditions, the follow up lasts until the implant has osseointegrated (4 months).

The assessment of primary implant stability at the surgical time is completed for all three groups by Torque (N/cm, rotational stability) and implant stability quotient (ISQ) that measures the axial stability. The follow up during the healing time after implant placement consisted on the measures of ISQ in the three groups. The times of assessment of the ISQ are 15, 30, 45 and 60 or more days in all the groups in the cases that the primary stability is high according to the protocol (45 Newton per cm or more insertion torque and 60 or more ISQ value). The last measure (60 or more days) is determined by the bone/implant healing of each patient.

Intervention Type
Other

Primary outcome measure
Dental implants primary stability is assessed using Insertion Torque (IT) and Implant Stability Quotient (ISQ) measurements after implant placement.

Secondary outcome measures
Dental implants secondary stability and its progression is asssessed using Implant Stability Quotient (ISQ) at 15, 30, 45 and 60 days.

Overall study start date
26/09/2013

Completion date
23/07/2016

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. In good medical and oral condition

3. Need one or more dental implants in the posterior maxilla, for supporting fixed rehabilitations (single crowns or fixed partial prostheses)
4. Willing to fully participate in the study, attending all the requested follow-up sessions

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40-60

Key exclusion criteria
1. Uncontrolled systemic diseases (uncompensated oral diabetes)
2. History of head/neck irradiation
3. Haemophilia
4. Immune system severe deficiencies
5. On pharmacological therapies that could alter bone metabolism (patients treated with oral /intravenous amino- bisphosphonates)
6. Pregnancy and lactation
7. Smoking >20 cigarettes/day (heavy smokers)

Date of first enrolment
01/09/2014

Date of final enrolment
03/01/2016

Locations

Countries of recruitment
Portugal

Study participating centre
Clinica Médico-Dentária RZG
Rua de Santa Cruz Lt 14 r/ch Fracção B
3850-127 Albergaria-a-Velha
Oporto
Portugal
3850-127

Sponsor information

Organisation
University of Porto

Sponsor details
Department of Oral Surgery
Faculty of Dental Medicine
University of Oporto
Rua Manuel Pereira da Silva
Oporto
Portugal
4200-393
+351 (0)220 901 100
raquelzitagomes@hotmail.com

Sponsor type
University/education

Website
https://sigarra.up.pt/up/pt/web_base.gera_pagina?p_pagina=universidade

ROR
https://ror.org/043pwc612

Funder(s)

Funder type
University/education

Funder Name
Universidade do Porto

Alternative Name(s)
University of Porto, U.Porto, UPorto

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Portugal

Results and Publications

Publication and dissemination plan
The study will be submitted for publication to Biomedical Research International, Tissue Engineering section.

Intention to publish date
10/10/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Rute Alexandra Borges de Almeida (rbalmeid@fc.up.pt)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2017		Yes	No