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Clinical study evaluating the survival and success rates of two dental implants with a narrow diameter made of a titanium-zirconium alloy supporting a dental bridge

Submission date
22/10/2017

Recruitment status
No longer recruiting

Registration date
28/11/2017

Overall study status
Completed

Last Edited
30/08/2023

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 a treatment to replace lost teeth. At the time of tooth loss, the jaw bone begins to atrophy (waste away). Standard diameter implants need a considerable amount of bone around them. Faced with a situation of bone atrophy, the surgeon has the option to reconstruct the bone through bone grafts to place standard implants or take advantage of the remaining bone and place implants with a smaller diameter. Implants with a reduced diameter are less resistant than standard diameter implants, so their use is somewhat controversial. One way to avoid fractures of these small diameter implants is to use stronger materials. A few years ago, the researchers began using a titanium-zirconium alloy (Roxolid) that is more resistant. In addition to its higher strength, it is more biocompatible (less harmful to the body) than other alloys. Small diameter implants can be used to safely replace anterior (front) teeth. Its use in posterior areas (back teeth) or in sections of two or more teeth requires more research. The aim of this study is to assess the survival and success of a treatment for an area of three or four missing teeth using a bridge supported by two small diameter implants made of titanium-zirconium.

Who can participate?
Patients aged 18 and over with an area of three or four missing teeth

What does the study involve?
Two titanium-zirconium narrow-diameter implants are placed under local anaesthetic. Only minor bone regeneration or soft tissue grafting is performed if needed. The crowns are placed after at least 8 weeks of healing. The success and survival rate of the implants is assessed 12 months after the final restoration.

What are the possible benefits and risks of participating?
Participants receive innovative but safe treatment. Participants also benefit from a reduced cost of treatment. The small diameter implants have been tested before and no different surgical or prosthetic complications are anticipated than in the placement of standard diameter implants.

Where is the study run from?
Universitat Internacional de Catalunya (Spain)

When is the study starting and how long is it expected to run for?
December 2011 to July 2021

Who is funding the study?
1. Universitat Internacional de Catalunya (Spain)
2. Institut Straumann AG (Switzerland)

Who is the main contact?
1. Dr Jose Nart
2. Dr Pablo Altuna

Contact information

Type(s)
Scientific

Contact name
Dr Pablo Altuna

ORCID ID
http://orcid.org/0000-0001-8977-849X

Contact details
Josep Trueta s/n
Sant Cugat del Vallès
Spain
08195

Type(s)
Scientific

Contact name
Dr José Nart

Contact details
Josep Trueta s/n
Sant Cugat del Vallès
Spain
08195

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IMP-ECL-2012-01

Study information

Scientific Title
Prospective clinical study of Straumann NNC dental implants for the treatment of partially edentulous patients

Study objectives
The hypothesis is that titanium-zirconium narrow diameter implants are a less invasive and successful when used in partially edentulous patients. Titanium-zirconium is a relatively new alloy used to manufacture dental implants. It is considered stronger than TCp, but clinical studies using narrow-diameter implants with this material are scarce.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board of Clinical Investigations of the Faculty of Dentistry, Universitat Internacional de Catalunya (Comitè Ètic d'Investigació Clínica (CEIC) of the Clinica Universitària d'Odontologia (CUO), Universitat Internacional de Catalunya, Barcelona), 16/07/2012, ref: IMP-ECL-2012-01

Study design
Prospective clinical trial of a cohort study with a follow-up from 1 year to 5 years

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Partially edentulous patients, missing 3 or four teeth in both jaws

Interventions
Thirty patients with partial edentulism (missing 3 or 4 teeth from second premolar to second premolar of both jaws) will be recruited for the study at the School of Dentistry's Clinic, Universitat Internacional de Catalunya, Barcelona. Two titanium-zirconium alloy (Roxolid (R)) narrow-diameter implants will be placed in each patient under local anesthesia. Rehabilitation with a bridge of 3 or 4 crowns. Only minor bone regeneration or soft tissue grafting would be performed if needed. The crowns would be placed after at least 8 weeks of healing.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
Success and survival rate of Straumann NNC implants 12 months after final restoration:
1. The success rate will be assessed according to the criteria of Buser (Buser et al., 1991):
1.1. No detectable clinical mobility (hand testing)
1.2. No radiolucency surrounding the total surface of the implant
1.3. No persistent pain refractory to medical therapy
1.4. No recurrent peri-implant infection
2. A surviving implant is an implant that is in place at the time of evaluation

Secondary outcome measures
Measured after 1 year, 3 years and 5 years:
1. Radiological measurements of the crestal bone level (mesial and distal), with bite registration and paralleling technique
2. Patient satisfaction and dentist satisfaction, measured using VAS
3. Periodontal evaluation: clinical attachment level, bleeding on probing, plaque index, pocket probing depth
4. Vestibular bone stability, measured using a small field CBCT
4. Survival, success and complications of the prostho treatment

Overall study start date
23/12/2011

Completion date
20/07/2021

Eligibility

Key inclusion criteria
1. Patients ≥18 years of age
2. Patients in need of multiple teeth restoration in the maxilla or mandible, of incisors, canines and bicuspids

3. Patients with narrow ridges where conventional implants with a diameter of 4.1 mm cannot be used (< 6 mm)
4. Patients with a full mouth plaque according to O'Leary ≤ 25% at time of surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Patients with any conditions or circumstances which would interfere with the requirements for oral surgery
2. Patients allergic to any implant metallic component
3. Patients needing major bone regeneration techniques
4. Patients where the ridge allows the restoration with a conventional implant diameter of 4.1 mm

Date of first enrolment
15/09/2012

Date of final enrolment
09/03/2016

Locations

Countries of recruitment
Spain

Study participating centre
Universitat Internacional de Catalunya
Josep Trueta s/n
Sant Cugat del Vallès
Spain
08195

Sponsor information

Organisation
Universitat Internacional de Catalunya

Sponsor details
Josep Trueta s/n
Sant Cugat del Vallès
Spain
08195
+34 (0)935 042 000
info@uic.es

Sponsor type
University/education

Website
www.uic.es

ROR
https://ror.org/00tse2b39

Funder(s)

Funder type
University/education

Funder Name
Universitat Internacional de Catalunya

Funder Name
Institut Straumann AG (Switzerland)

Results and Publications

Publication and dissemination plan
Publication of 1-year, 3 years and 5 years results

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Pablo Altuna. After written request and after the 5 year results

publication (December 2022), data could be shared after evaluating the credentials of the soliciting investigator and his/her Institution. After acknowledging the written request, authorization by the Dean and/or Research Vice-Dean must be obtained to hand out the requested datasets. All datasets would be blinded regarding patient identification. All patients have signed a proper study informed consent.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2023	30/08/2023	Yes	No