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Grant Dental Technologys Proximerge™ Implant System post-market clinical study

Submission date	Recruitment status	[ ] Prospectively registered
26/07/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/10/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/10/2013	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The Proximerge™ Implant System (Proximerge) has been designed and manufactured by Grant Dental Technology Corporation (GDTC). It is used for single or multiple dental prosthetic restorations used in the jaw region to support chewing function. Proximerge first received CE marking as a Class IIb medical device in August 2012 and has been sold in the UK since November 2012.
The main objectives of this study are: to assess the implant survival rates at one and two year intervals and the success rates of implant at one and two year intervals.
The study will:
Provide continued clinical evidence on the performance and safety of the device
Collect data on the safety and performance of the device under normal conditions of use
Identify any risks when used according to intended purpose assigned by the manufacturer (Grant Dental Technology Corporation)

Who can participate?
Subjects (men and women) at least 25 years of age, meeting the requirements for a dental implant.

What does the study involve?
The study involves routine dental implant placement and routine oral hygiene care.
The dentist or implant surgeon will take x-rays of the subject's jaw, paying special attention to the area which will be treated. A general review of these x-rays will allow the dentist to carefully inspect for any additional teeth or areas in the bone that require treatment (whether for implants or otherwise). Other tests are required to properly proceed with implant treatment. A full examination of mouth is required to determine if gum disease is present and, if so, provide an effective treatment plan. A complete tooth-by-tooth examination is also necessary to identify and properly treat any active cavities or other dental problems.
Dental impressions are needed at various points of treatment to assess the status of the subject's bite and proceed with proper restoration of the implants in line with the rest of the subjects entire arrangement of teeth. Photographs may also be used to help plan the subjects treatment as well as record the subjects progress.

What are the possible benefits and risks of participating?
Proximerge dental implant device provides a structural platform that is geometrically similar and functionally equivalent to common circular implants while providing more space (width) to match the natural molar (jaw) footprint. All major aspects of the system have been engineered to include commonly employed design characteristics, which have proven successful in other devices on the market.
Patients participating in this study are subject to risks no greater than, or are similar to, the risks associated with undergoing a dental implant placement. All of the study complications will be recorded and analysed in order to evaluate their significance, and a complete report will be written on the findings.

Where is the study run from?
Grant Dental Technology Corporation, USA, is organising and funding the project. The study will be run from up to five sites in the UK.

When is the study starting and how long is it expected to run for?
The study started in August 2013 and the recruitment is expected to last for about six months. The study will run until July 2017.

Who is funding the study?
Grant Dental Technology Corporation, USA

Who is the main contact?
Carrie Hetrick, VP of Regulatory Affairs
Grant Dental Technology Corporation

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PROX-13-001

Study information

Scientific Title
A post market multi-center prospective study of the Grant Dental Technology Corporation (GDTC) Proximerge™ Implant System

Study objectives
This is a post-marketing clinical study designed to demonstrate safety and performance of the Proximerge™ Implant System in a single posterior tooth replacement.

The primary hypothesis is that the stability and bone integrity (the level of osseointegration) using the Proximerge™ Implant System from the time of implant to the completion of the final restoration is comparable to literature based performance goals for osseointegration and peri-implant tissue health.

The secondary hypothesis is that the Proximerge™ Implant System maintains osseointegration and bone integrity with equal or reduced peri-implantitis over a longer-term period of two years post implant.

The purpose of the clinical study is to provide post-market evaluation data on the performance of the CE Mark device Proximerge™ in a posterior implant dental procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Observational post-marketing multi-center prospective single-arm unblinded clinical study

Primary study design
Observational

Secondary study design
Other

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied

Single or multiple dental prosthetic restorations

Interventions
A post-marketing clinical study designed to demonstrate safety and performance of the Proximerge™ Implant System.

The device used in this study is a CE marked dental implant that is used as standard of care in tooth replacement surgery. The GDTC Proximerge™ Implant System is indicated for single or multiple dental prosthetic restorations used in the molar region to support masticatory function.

The study will involve up to five investigational sites in the United Kingdom. Total enrollment is expected to last approximately six months and the primary endpoint will be measured at six months post load. A longer-term analysis will occur at 24 months post load. Therefore, the overall study duration should be approximately 30 months and each subject will participate for 24 months when including the longer-term follow up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary efficacy endpoint is the amount of bone loss at 6 months after the time of implant using the Proximerge™ Implant System. The performance goals based on literature is less than 1.5 mm bone loss at 6 months.

The primary analysis will be a one sample T-test (two-sided) to determine if the bone loss is significantly different than the performance goal of 1.50 mm at 6 months.
The primary hypothesis to be tested is:
H0: PF = μT vs. H1: PF ≠ μT, where PF is the performance goal of 1.50 mm and μT is the population mean bone loss using Proximerge™ Implant System. The not equal sign is used because hypothesis testing is two-sided.

Secondary outcome measures
1. Comparative measurement between the Proximerge™ Implant System and a pre-determined performance goal (1.50 mm) of the amount of bone loss at 3, 9, 12, 18 and 24 months after the final crown is loaded.
2. Evaluation of implant ideal clinical condition based on the International Congress of Oral Implantologists (ICOI) Pisa Implant Quality Health Scale at 3, 6, 9, 12, 18 and 24 months after the final crown is loaded.
3. Evaluation of implant success based on the Implant-to-Crown Success Criteria at 3, 6, 9, 12, 18 and 24 months after the final crown is loaded.
4. Duration of implant success based the ICOI Pisa Implant Quality Health Scare (failure)
5. Evaluation of implant mobility (yes/no) and bone integrity (D5 or not D5) at 3, 6, 9, 12, 18 and 24 months after the final crown is loaded with the Proximerge™ Implant System.
6. Evaluation of dental implant associated peri-implant soft tissue health (bleeding index, plaque index, probe depth), at 3, 6, 9, 12, 18, and 24 months after the final crown is loaded with the Proximerge™ Implant System.
7. Evaluation of post market device related safety vigilance reporting.
8. Evaluation of all Unanticipated Adverse Device Effects (UADEs) including but not limited to

those that may be related to toxicity from the device.
9. Evaluation of all Serious Adverse Events (SAEs) incurring during the study.

Overall study start date
01/08/2013

Completion date
30/07/2017

Eligibility

Key inclusion criteria
The enrollment population for this clinical study will be selected from subjects scheduled to undergo an elective posterior maxilla or mandibular implant placement to restore a missing posterior tooth. A potential subject will be included in the study if he/she meets all of the following inclusion criteria:
1. At least 25 years of age, either sex
2. Demonstrate adequate oral hygiene (defined as an average Modified Sulcus Bleeding Index of ≤ 1 and an average Modified Plaque Index of ≤ 1)
3. The location of the proposed implant must be a bounded edentulous space
4. Bone Quality Index (BQI) of Type II (D2) or III (D3) bone
4.1. Type II (D2) bone is defined as thick cortical bone with marrow cavity or
4.2. Type III (D3) bone is defined as thin cortical bone with dense trabecular bone of good strength
5. In the opinion of the investigator, demonstrate absence of any medical conditions, psychological illness, or social conditions that may potentially impact the safety and welfare of the subject or a favorable outcome with the implant (uncontrolled diabetes, malignancies, alcoholism, drug abuses, non-permanent housing, incarceration, etc.)
6. Willingness, ability and commitment to comply with all requirements for the full length of the study
7. Provided written informed consent to participate in the study signed by the subject or a legal representative

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
The number of subjects needed to perform the primary efficacy analysis is 34 subjects. An approximate dropout of 18% will be assumed. Therefore, 40 subjects will be enrolled.

Key exclusion criteria
A potential subject will be excluded from the study if he/she meets any of the following criteria:
1. Inadequate bone volume to accommodate the planned endosseous dental implant. Inadequate bone volume defined as edentulous space dimensions unable to accommodate

implant dimensions of <6.5 mm ridge width (facial-lingual), <8 mm in the mesial to distal dimension, and/or <10 mm in implant length (i.e. 9 mm facial-lingual, 11 mesiodistal, 12 mm depth)
2. Active periodontal infections or untreated periodontitis
3. History of radiation treatments to the head and/or neck
4. Potential need for post implant bone grafting at the implant recipient site or previous bone grafting within six months due to inadequate bone volume
5. History of parafunctions, (i.e. severe bruxing or clenching habits)
6. Active systemic infection or any other health condition that would preclude elective surgery
7. A tooth extraction at the implant site within the previous two months
8. Presence of local inflammation or mucosal diseases such as lichen planus
9. Subjects with a history of hematologic disorders or currently taking warfarin, dabigatran or other similar oral anticoagulants
10. History of intravenous (IV)-based bisphosphonates use
11. Subjects not willing to provide informed consent
12. Pregnancy

Date of first enrolment
01/08/2013

Date of final enrolment
30/07/2017

Locations

Countries of recruitment
United Kingdom

United States of America

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Grant Dental Technology Corporation (USA)

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