ISRCTN41619166 https://doi.org/10.1186/ISRCTN41619166

Evaluation of using calcium sulfate bone graft (DentoGen ®) as a material to enhance bone width in front of dental implants

Submission date 12/04/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 16/04/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/04/2020	**Condition category** Oral Health	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Dental implants are artificial replacements for tooth roots that are placed within the bone of the jaw so that they can be used to support dentures, crowns (caps) or bridges.
In some patients there is not enough bone in their jaw to allow dental implants to be inserted. In cases where a lot of bone is needed, it may be possible to rebuild the jaw using bone taken from another part of the body. DentoGen® is a new bone graft product that can be used in place of bone.
The aim of this study is to evaluate the efficacy of using calcium sulfate bone graft (bone substitute with commercial name DentoGen®).

Who can participate?
Patients aged 25 – 65 years with tooth loss in the anterior area of the maxilla extracted at least 3 months before the study.

What does the study involve?
Patients undergo dental implant surgery as normal using the bone substitute material in place of a usual bone graft. Patients are followed up after four months.

What are the possible benefits and risks of participating?
The possible benefits are to gain bone in the buccal side of the dental implants so that means we could achieve one stage implantation with GBR by a new method using a reliable material allowing us to:
1. Dispense the use of collagen membrane and titanium mesh
2. Reduce the overall treatment plan time in these cases from nearly a year to just 4 months
3. Give the ability to treat the patient with bone loos by dental implant without expose them for more than 1 surgery.
The possible risk is to not having a perfect bone remodelling on the margin of the buccal side of the implant which will slightly effect the aesthetic side of the area

Where is the study run from?
Faculty of Dentistry of Damascus University (Syria)

When is the study starting and how long is it expected to run for?
June 2019 to May 2020

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluation of the effectiveness of using calcium sulfate bone graft in the context of immediate grafting around dental implants

Study objectives
Calcium sulfate from (DentoGen ®) is effective as a bone grafting material

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/05/2019, Scientific research committee in the faculty of dentistry at Damascus University (Mazzeh Highway, Damascus, Syria; +963113341864; manager@hcsr.gov.sy), ref: 557

Study design
Prospective interventional study

Primary study design
Interventional

Secondary study design
Prospective interventional 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
Bone grafting in the buccal side of dental implants when the bone is thin

Interventions
After local anesthesia a full-thickness flap is made in the implantation site, the best place of the implant in point and axes is determined, a very thin layer of bone is left buccally after socket preparation then the implant is inserted then the graft (CS) is mixed and the buccal bone layer dried by Gauze, after that apply the material on the buccal side by layers and making pressure on it by Gauze moisturizer with the combined solution waiting 2 - 4 minutes until the graft is solid then make sure that the flap can be sutured free of tension to make a firm closure using 4-0 nylon sutures.

Next day a CBCT image is taken of the implantation area, measured to determine the width of the site, the amount of the gain, graft and bone density.

The sutures are removed 8 - 10 days after the surgery.
After 4 months the final CBCT image is taken to do the same measurements and compare it with the previous ones to determine the final width of the site, the amount of the gain, graft and bone density and the resorption rate of the graft.

Intervention Type

Procedure/Surgery

Primary outcome measure
Using CBCT imaging technique:
1. Width of the bone in the grafted area the day after the procedure and at 4 months
2. Bone and graft density buccally to the implants the day after application and after 4 months
3. Resorption rate of the graft by comparing measures taken the day after and 4 months after

Secondary outcome measures
1. Width in the site of implantation the day after the procedure and at 4 months using CBCT imaging technique
2. The thickness of attached gingiva in the area of implantation before the procedure and 4 months after using CBCT imaging technique
3. The success rate at 4 months (further surgery required, yes or no)

Overall study start date
14/05/2019

Completion date
01/05/2020

Eligibility

Key inclusion criteria
1. Patient with tooth loss in the anterior area of the maxilla extracted at least 3 months before the study.
2. Healthy patient with no general diseases and no medication intake.
3. Aged 25 - 65 years
4. Width of the alveolar ridge 3.5 - 5.5 mm on a diagnostic CBCT image
5. Non smoking

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
12

Key exclusion criteria
1. Newly extracted teeth in the area of tooth lost
2. General diseases or medication intake
3. Bad oral hygiene or smoking

Date of first enrolment
17/06/2019

Date of final enrolment
05/11/2019

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Faculty of Dentistry
Mazzeh Highway
Damascus
Syria
-

Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

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https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/09/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date