Sinus Floor Elevation Using Alpha-Bio's GRAFT Natural Bovine Bone vs. Commercially Available Bone Graft

This study is ongoing, but not recruiting participants.

Sponsor:
Alpha - Bio Tec Ltd.

Information provided by (Responsible Party):
Alpha - Bio Tec Ltd.

ClinicalTrials.gov Identifier:
NCT02384291

First received: February 26, 2015
Last updated: January 24, 2017
Last verified: January 2017
History of Changes

Purpose

This clinical study is designed to compare the regenerative outcome of using separately two different Xenografts during sinus floor augmentation.

Aim of this prospective randomized-controlled clinical trial is to compare the regenerative results of Alpha-Bio's GRAFT Natural Bovine Bone versus commercially available bone graft after two-step sinus floor elevations by clinical and histological analysis.

Clinical Parameters are wound healing parameters, radiological volume stability and implant survival rates. Histological parameters are based on a histomorphometrical analysis of trephine cores harvested in progress of implant bed preparation.

Condition	Intervention
Sinus Floor Augmentation	Device: **Alpha-Bio** GRAFT Natural Bovine Bone Device: natural bone substitute

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Participant
Primary Purpose: Treatment

Official Title: Sinus Floor Elevation Using **Alpha-Bio's** GRAFT Natural Bovine Bone Versus Commercially Available Bone Graft. A Prospective Randomized Clinical Trial

Resource links provided by NLM:

MedlinePlus related topics: Bone Grafts

U.S. FDA Resources

Further study details as provided by Alpha - Bio Tec Ltd.:

Primary Outcome Measures:

- Histological bone formation following sinus floor augmentation [evaluated by biopsies harvested from the implant sites] [Time Frame: 6 months]

Secondary Outcome Measures:

- Bone volume-stable results six months following augmentation procedures [demonstrated by X-ray evaluation]. [Time Frame: 6 months]

Enrollment: 44
Study Start Date: May 2014
Estimated Study Completion Date: December 2017
Estimated Primary Completion Date: December 2017 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: **Alpha-Bios** GRAFT Natural Bovine Bone treatment Pure Hydroxyapatite ceramic mineral with high similarity to the human bone	Device: **Alpha-Bio** GRAFT Natural Bovine Bone Pure Hydroxyapatite ceramic mineral with high similarity to the human bone
Active Comparator: natural bone substitute natural bone substitute material derived from the mineral portion of bovine bone	Device: natural bone substitute natural bone substitute material derived from the mineral portion of bovine bone

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. Patients who will present with a moderately or severely atrophic posterior maxilla with 1-6 mm residual alveolar bone will be selected for the study.
2. Men and women over the age of 18 years.
3. Patient has signed the Informed Consent.

Exclusion Criteria:

1. Chronic steroid therapy,
2. Uncontrolled diabetes,
3. Cardiovascular disease,
4. Past irradiation of head and neck
5. Maxillary sinus cysts,
6. Active chronic sinusitis,
7. Smoking more than ten cigarettes per day during the 3 months preceding this study .
8. Malignant disease in the 5 years preceding this study
9. Uncontrolled bleeding disorders such as: hemophilia, thrombocytopenia, granulocytopenia

10. Disease that compromise the immune system
11. Psychiatric disorder
12. Hypersensitivity to titanium, collagen or bovine bone.
13. Women who are pregnant or nursing.
14. Patients with non-treated periodontal disease.
15. Medical and/or general contraindications for intraoral surgical procedures

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02384291

Sponsors and Collaborators

Alpha - Bio Tec Ltd.

Investigators

Principal Investigator: Daniel Rothamel, Priv-Doz Dr. Department of Craniomaxillofacial and Plastic Surgery University Hospital of Cologne

More Information

Additional Information:

Sponsor site EXIT

Responsible Party:	Alpha - Bio Tec Ltd.
ClinicalTrials.gov Identifier:	NCT02384291 History of Changes
Other Study ID Numbers:	ABT-BG-01
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