A Multi-center Study to Evaluate Bone Loss, Survival Rate and Stability of SPI Implant (SPI)

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:
NCT02367261

First received: February 12, 2015
Last updated: March 27, 2016
Last verified: March 2016
History of Changes

Purpose

The current prospective clinical study's aim is to determine ABT's SPI implant survival rate, crestal interproximal bone resorption during 24 months post implant insertion and to assimilate the drilling sequence during the clinical use of SPI implants.

Condition	Intervention	Phase
Implant Clinical Survival Dental Implant Bone Loss	Device: SPI implant	Phase 4

Study Type: Interventional
Study Design: Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: An Open, Prospective, Multi-center Study to Evaluate Bone Loss, the Survival Rate of SPI Implant System and Implant Stability Over a 24 Months, in Patients With Tooth Loss Requiring up to 4 Implants, in Staged Loading Protocol.

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

Primary Outcome Measures:

- Cumulative Survival Rate [Time Frame: 24 months]

Estimated Enrollment: 90
Study Start Date: November 2014
Estimated Study Completion Date: May 2017
Estimated Primary Completion Date: May 2017 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: SPI dental implant Subjects implanted with SPI implant	Device: SPI implant SPI implant - the original spiral implant

Eligibility

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

Criteria

Inclusion Criteria:

1. Men and women over the age of 18 years who need implantation of 1-4 implants.
2. Patients who are able to understand the requirements of the study, and are willing and able to comply with its instructions and schedules.
3. Patients who had provided written informed consent to participate in the study prior to any study procedure.
4. Patients in general good health in the opinion of the principal investigator as determined by medical history and oral examination.

Exclusion Criteria:

1. Immediate loaded implants.
2. Patient requiring bone augmentation
3. Treatment with anticoagulant drugs (INR under 1.8) or bisphosphonates.
4. Treatment with anticonvulsants drugs.
5. Untreated Periodontal disease and inability of the patient to maintain reasonable oral hygiene according to study requirements.
6. Patients with history of alcohol, narcotics or drug abuse.
7. Patients under steroid therapy.
8. Patients receiving radiotherapy, chemotherapy or any other immunosuppressive treatment or who have been administered radiotherapy in the last 5 years. Patients through at anytime received radiotherapy to the head and neck region will be excluded anyway.
9. Metabolic bone disorders and/or bone augmentation.
10. Uncontrolled bleeding disorders such as: hemophilia, thrombocytopenia, granulocytopenia.

11. Degenerative diseases.
12. Osteoradionecrosis.
13. Renal failure.
14. Organ transplant recipients.
15. HIV positive.
16. Malignant diseases.
17. Diseases that compromise the immune system.
18. Unbalanced diabetes mellitus. (HbA1c above 6.5)
19. Psychotic diseases.
20. Hypersensitivity to one of the components of the implant in general and titanium in particular.
21. Women who are pregnant or lactating.
22. Lack of patient cooperation.
23. Uncontrolled endocrine diseases.
24. Any systemic condition that is unbalanced and therefore precludes surgical procedures.
25. Parafunctional habits.- e.g Bruxism.
26. Temporomandibular joint disease.
27. Various pathologies of the oral mucosa for example: Benign mucous pemphigoid, desquamative ginigivitis, erosive lichen planus ,malignancy of oral cavity, bolus erosive diseases of the oral mucosa.
28. Flapless 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: NCT02367261

Locations

China, Sichuan

West China Hospital of Stomatology
Chengdu, Sichuan, China

China

West China Hospital of Stomatology
Jinan, China

The Affiliated Stomatology Hospital of Tongji University
Shanghai, China

Stomatology Hospital of Shandong University
Yantai, China

Sponsors and Collaborators

Alpha - Bio Tec Ltd.

Investigators

Principal Investigator: Yi Man, Dr West China Hospital of Stomatology, Chengdu, Sichuan China

More Information

Additional Information:

Sponsor's site EXIT

Responsible Party: Alpha - Bio Tec Ltd.
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Other Study ID Numbers: SPI-001
Study First Received: February 12, 2015
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ClinicalTrials.gov processed this record on March 10, 2017

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