

Trial record **1 of 1** for: ABT-ME-130815

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## Central Incisors Narrow Implants in Alternative to Bone Augmentation With 4.2 mm Implants .

**This study is currently recruiting participants.** (see [Contacts and Locations](#))

*Verified September 2016 by Alpha - Bio Tec Ltd.*

**Sponsor:**

Alpha - Bio Tec Ltd.

**Information provided by (Responsible Party):**

Alpha - Bio Tec Ltd.

**ClinicalTrials.gov Identifier:**

NCT02897193

First received: September 1, 2016

Last updated: September 22, 2016

Last verified: September 2016

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**▶ Purpose**

Horizontal bone augmentation procedures are commonly used to increase bone width to allow the placement of dental implants or to improve aesthetics in deficient areas. Smaller diameter implants could be used instead in order to avoid bone augmentation procedures.

The comparison between these two solutions will be evaluated in the trial.

Condition	Intervention	Phase
Upper Central Incisor Edentulism	Device: ICE dental implant 4.2 mm Device: NICE dental implant 3.2 mm Device: Alpha Bio's Graft Bovine bone Device: Alpha Bio's Graft resorbable membrane	Phase 4

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

Official Title: 3.2 mm Diameter Implants and Soft Tissue Grafts in Alternative to Horizontal Bone Augmentation for Placing 4.2 mm Diameter Implants at Central Incisors. A Multicenter Randomised Controlled Trial

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

Primary Outcome Measures:

- bone loss [ Time Frame: 2 years ]  
bone loss level as will be measured from the radio-graphic images

Secondary Outcome Measures:

- Cumulative implant survival [ Time Frame: 2 years ]  
Counting number of survived implants at the end of the study

Estimated Enrollment: 42  
Study Start Date: August 2016  
Estimated Study Completion Date: December 2018  
Estimated Primary Completion Date: September 2018 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Dental implant with bone augmentation patients will be installed with ICE Dental implant 4.2 mm diameter with Alpha-Bio's grafts horizontal bone augmentation	Device: ICE dental implant 4.2 mm ICE dental implant 4.2 mm diameter Device: Alpha Bio's Graft Bovine bone Alpha Bio's Graft Bovine Bone Device: Alpha Bio's Graft resorbable membrane Alpha Bio's Graft resorbable collagen membrane
Experimental: narrow implant patients will be installed with NICE Dental implant 3.2 mm diameter	Device: NICE dental implant 3.2 mm NICE dental implant 4.2 mm diameter

## ► Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

### Criteria

#### Inclusion Criteria:

- Upper central incisor edentulism
- bone width between 3.5-4.5 mm
- requirement of only one implant supported crown
- patient is willing to sign an informed consent

#### Exclusion Criteria:

- General contraindications to implant surgery.
- Immunosuppressed or immunocompromised patients
- Patients irradiated in the head and neck area.
- Patients with poor oral hygiene and motivation.
- Uncontrolled diabetes.
- Pregnancy or lactation.
- Addiction to alcohol or drugs.
- Untreated periodontal disease.
- Treated or under treatment with intravenous amino-biphosphonates.
- Poor oral hygiene and motivation.
- Psychiatric problems and/or unrealistic expectations.
- Acute infection (abscess) or suppuration in the area intended for implant placement.
- Patients referred only for implant placement if cannot be followed at the treatment centre.
- Patient unable to attend the follow-up controls for 3 years after implant loading.
- Patient included in other studies, if this protocol cannot be properly followed.
- Immediate post-extractive sites (to be eligible at least 3 months must have passed since extraction).

## ► 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](#).

## Contacts

Contact: Jorge Jofre, Dr. +56 41 220 3770 [jjofre@crai.cl](mailto:jjofre@crai.cl)

## Locations

### Chile

University of Antofagasta **Recruiting**  
Antofagasta, Chile  
Contact: Hiroshy Contreras, Dr [hirocks98@gmail.com](mailto:hirocks98@gmail.com)

Andrés Bello National University **Recruiting**  
Santiago, Chile  
Contact: Luis Honorato, Dr. [honorato.luis@gmail.com](mailto:honorato.luis@gmail.com)

## Sponsors and Collaborators

Alpha - Bio Tec Ltd.

## ▶ More Information

Additional Information:

[sponsor site](#) 

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ClinicalTrials.gov Identifier: [NCT02897193](#) [History of Changes](#)  
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Study First Received: September 1, 2016  
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