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A prospective, multicenter, randomized, positive-controlled, non-inferiority clinical study to evaluate the effectiveness and safety of resorbable biological membrane-Bonamem™ Collagen Membrane for alveolar bone defect repair

Submission date 24/11/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 27/11/2025	**Overall study status** Completed	
Last Edited 25/11/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Guided Bone Regeneration (GBR) is a surgical technique that involves placing an oral biological membrane between oral soft tissue and bone defects to separate different tissues and create a biological barrier. This establishes a relatively closed environment for bone regeneration and selectively prevents the faster-migrating fibroblasts and epithelial cells from entering the bone defect area, while not hindering the natural healing of the wound, achieving the goal of tissue regeneration and directed repair. Acellular Porcine Pericardium (APP) has been proven to have good biological properties in clinical surgical repair and is mainly composed of Type I collagen. The purpose of the clinical trial is to evaluate the effectiveness and safety of the resorbable biological membrane produced by Bonanga for the repair of alveolar bone defects.

Who can participate?
Patients aged 18 to 65 years who have alveolar bone defects preoperatively and require alveolar bone defect repair at the same time as tooth extraction.

What does the study involve?
Eligible subjects for this trial will be randomly assigned to the experimental group and the control group in a 1:1 ratio. The experimental group will use the experimental device—Bonamem™ Collagen Membrane from BONANGA + Bio-Oss, while the control group will use the control device—Geistlich Bio-Gide from Geistlich Pharma AG + Bio-Oss. The change in alveolar bone height at 6 months postoperatively compared to immediately postoperatively in the experimental group will be evaluated(by observing the imaging results from CBCT (Cone Beam

Computed Tomography).) to determine if it is non-inferior to that of the control group, thereby verifying the effectiveness and safety of BONANGA's resorbable biological membrane-Bonamem™ Collagen Membrane for bone defect repair in clinical use.

What are the possible benefits and risks of participating?
Subjects can benefit from alveolar bone defect repair and related medical services during this clinical study. Participation in this study involves no major risks; however, related common treatment reactions (e.g., gingival swelling and redness, gingival bleeding, local inflammatory reactions) may occur. Most of these are mild and will spontaneously subside or disappear within a few days post-operation without requiring intervention.

Where is the study run from?
The trial is conducted at five clinical trial centers. The leading unit is Wuhan University School of Dentistry, Wuhan, China.

When is the study starting and how long is it expected to run for?
December 2022 to July 2024

Who is funding the study?
Bonanga Technology Tianjin Co.,Ltd.,China

Who is the main contact?
Mrs.Sun
sunym@bonanga.com

Contact information

Type(s)
Scientific, Public, Principal investigator

Contact name
Mr Zhixu Jiang

ORCID ID
https://orcid.org/0009-0009-2813-6560

Contact details
Room 203, building 11, No.6, Hechang Road, Wuqing development zone
Tianjin
China
301700
+86 18202699815
jiangzx@bonanga.com

Additional identifiers

Study information

Scientific Title

A prospective, multicenter, randomized, positive-controlled, non-inferiority clinical study to evaluate the effectiveness and safety of resorbable biological membrane-Bonamem™ Collagen Membrane for alveolar bone defect repair

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/01/2023, The Ethics Committee of School & Hospital of Stomatology, Wuhan University (No. 237, Luoyu Road, Hongshan District, Wuhan, 430070, China; +86 27-87686250; wdkqllwyh@163.com), ref: [2022](10)

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Research on the application of resorbable biological membrane-Bonamem™ Collagen Membrane for alveolar bone defect repair.

Interventions
Informed consent will be obtained from all participants prior to enrollment.This is a prospective, multicenter, randomized, active-controlled, non-inferiority clinical trial conducted at 5 clinical centers with 160 enrolled subjects. Eligible subjects are randomly assigned to the test group and control group in a 1:1 ratio.
The test group uses the test device – resorbable collagen membrane from BONANGA + Bio-Oss bone graft material, while the control group uses the control device – Geistlich Bio-Gide resorbable collagen membrane from Geistlich Pharma AG, Switzerland + Bio-Oss bone graft material. The trial evaluates whether the change in alveolar bone height at 6 months postoperatively compared to immediately after surgery in the test group is non-inferior to that in the control group, so as to verify the efficacy and safety of the resorbable collagen membrane

from BONANGA for clinical application in bone defect repair.
All surgical procedures will be performed per protocol to ensure standardization of the trial process.

This trial employs block randomization for clinical research.
The randomization numbers for the subjects are provided by an independent statistician, who generates a set of random numbers using the PLAN procedure in SAS 9.4 or a higher version on an electronic computer. According to these random numbers and the established rules, subjects are randomly assigned to the experimental group or the control group in a 1:1 ratio. The specific method of randomization involves using sealed random envelope, which are distributed sequentially to cases that have qualified for screening. The sealed random envelope is opened to determine the treatment with the corresponding device, and each random number itself does not indicate the patient's group or method of examination.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Absorbable oral biomembrane

Primary outcome(s)
1. Alveolar bone height measured using Cone Beam Computed Tomography (CBCT) at immediately after surgery and at 6 months postoperatively

Key secondary outcome(s)
1. Mesiodistal alveolar bone width measured using Subjects undergo Cone Beam CT (CBCT) imaging (independent evaluators, who are not part of this study, analyze and measure the change in the mesiodistal alveolar bone width based on the imaging results using the same software) at immediately after surgery and at 6 months postoperatively

2. Wound Healing measured using wound healing assessment scale (the gingival tissue at the material implantation site will be assessed) at 12 Days Post-Operation

Completion date
27/03/2024

Eligibility

Key inclusion criteria
1. The subject voluntarily participates in the trial and signs a written informed consent form;
2. Aged between 18 and 65 years old (including 18 and 65 years old), with no gender restrictions;
3. Cases with alveolar bone defects in the socket wall, with the maximum vertical height of the bone defect ≥5mm after tooth extraction; or cases with normal mesiodistal alveolar bone height of the second molar and a distal alveolar defect ≥5mm after extraction of the third molar;
4. At least one healthy adjacent tooth on one side.

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
160

Key exclusion criteria
1. Bone defects caused by invasive or malignant bone tumors;
2. Patients with osteoporosis or osteomalacia;
3. Individuals with a specific allergic constitution, especially those sensitive to collagen;
4. Those who refuse to use pig-derived medical products;
5. Pregnant or nursing women and those planning to become pregnant during the study period;
6. Individuals with contraindications for oral surgery;
7. Those with systemic diseases that may affect the postoperative healing period and/or osseointegration, such as diabetes (fasting blood glucose ≥8 mmol/L), uncontrolled hypertension (systolic ≥160 mmHg and/or diastolic ≥100 mmHg), thyroid diseases, etc.;
8. Systemic or local bone diseases, such as tuberculosis, osteomyelitis, bone tumors, etc.;
9. Individuals with apical lesions in adjacent teeth in the surgical area, or those with apical cysts;
10. Individuals with uncontrolled systemic infections;
11. Severe hematological disorders, such as leukemia or other bleeding disorders;
12. Abnormal coagulation function (e.g., Prothrombin Time (PT) prolonged or shortened by >3 seconds, Activated Partial Thromboplastin Time (APTT) prolonged or shortened by >10 seconds, Platelet count (PLT) <50x10^9/L);
13. Patients with adjacent teeth that can cause artifacts in oral imaging examinations, such as metal dentures or porcelain crowns;
14. Patients with untreated periodontal disease or advanced periodontal disease;
15. History of radiotherapy to the head and neck within the last 3 years, or those currently undergoing radiotherapy or chemotherapy;
16. Patients currently using or using for a long term special medications that may affect postoperative healing or osseointegration (e.g., bisphosphonates and high doses of glucocorticoids);
17. Abnormal liver and kidney function (Alanine Aminotransferase (ALT) ≥1.5 times the Upper Limit of Normal (ULN) or Aspartate Transaminase (AST) >1.5 ULN, or creatinine ≥1.5 times ULN);
18. Alcohol abusers, drug addicts, or those with a tendency to addiction;
19. Individuals who smoke more than ten cigarettes per day;
20. Individuals in the acute phase of Hepatitis B infection;
21. Individuals with positive initial screening for Human Immunodeficiency Virus (HIV) antibodies, Hepatitis C antibodies, or Treponema pallidum-specific antibodies;
22. Individuals who have participated in other clinical trials within 3 months prior to the start of this trial;

23. Individuals with mental abnormalities and no capacity for autonomous behavior;
24. Individuals whom the investigator deems unsuitable to participate in this clinical trial for other reasons.

Date of first enrolment
15/02/2023

Date of final enrolment
18/09/2023

Locations

Countries of recruitment
China

Sponsor information

Organisation
Bonanga Technology Tianjin Co.,Ltd.

Funder(s)

Funder type

Funder Name
Bonanga Technology Tianjin Co.,Ltd.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available