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Evaluating a gel with hyaluronic acid and amino acids to improve bone healing after tooth extraction: a clinical study

Submission date 01/08/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 03/08/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 03/08/2026	**Condition category** Oral Health	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
When a tooth is removed, the surrounding bone naturally shrinks over time, which can make future dental treatments more difficult. Some existing techniques to preserve bone are complex, expensive, or not always suitable for all patients. This study aims to evaluate whether applying a gel containing hyaluronic acid and amino acids directly into the tooth socket can improve healing and support better bone regeneration after tooth extraction.

Who can participate?
Adults in good general health who need to have two similar teeth removed (on opposite sides of the mouth) due to severe decay or fractures may be eligible. Participants must not have active gum disease and should be able to attend follow-up visits.

What does the study involve?
Each participant undergoes tooth extraction on both sides of the mouth during the same appointment. On one side, the gel is applied into the socket after the tooth is removed, while the other side is left untreated as a comparison. This allows each patient to act as their own control. Follow-up visits are scheduled over several weeks to monitor healing, and a 3D radiographic scan is taken after about three months to assess bone regeneration.

What are the possible benefits and risks of participating?
Participants may benefit from improved healing after tooth extraction, although this cannot be guaranteed. The risks are similar to those of standard tooth extraction procedures, such as pain, swelling, or infection. The gel used in the study is already available for clinical use, and no additional major risks are expected beyond routine care.

Where is the study run from?
University Hospital “Policlinico di Bari” (Italy)

When is the study starting and how long is it expected to run for?
January 2023 to June 2026

Who is funding the study?
Universita degli Studi di Bari Aldo Moro (Italy)

Who is the main contact?
Dr Luisa Limongelli, luisa.limongelli@uniba.it

Contact information

Type(s)
Principal investigator, Public, Scientific

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Study information

Scientific Title
Use of a hyaluronic acid–based gel combined with an amino acid pool for maxillary bones regeneration: a randomized controlled split-mouth clinical study

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/10/2007, Comitato etico indipendente dell'Azienda Universitaria Ospedaliera Consorziale Policlinico di Bari (Piazza G. Cesare 11, Bari, 70124, Italy; +39 (0)805593399; comitato.etico@cimedoc.uniba.it), ref: Prot.n.21/C.E.

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Uncontrolled

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Post-extraction alveolar ridge regeneration

Interventions
Participants are enrolled in a randomized controlled split-mouth clinical trial. Each participant undergoes two comparable non-surgical tooth extractions performed during the same clinical session.

Following tooth extraction, one post-extraction socket (test site) receives a formulation of high-molecular-weight hyaluronic acid combined with amino acids (Aminogam Gel®), applied directly into the alveolus prior to suturing. The contralateral socket serves as the control site and does not receive any biomaterial.

Participants are allocated to test and control conditions using randomization, with each hemiarch assigned to either treatment or no-treatment control according to a randomized sequence.

All procedures are performed under local anesthesia using mepivacaine with adrenaline. The surgical approach is atraumatic and flapless, with odontotomy performed only when necessary. Both sites undergo curettage and suturing.

All participants receive the same postoperative protocol, including antibiotic therapy with amoxicillin and clavulanic acid (1 g every 12 hours for 6 days), analgesics as needed, and oral hygiene instructions with chlorhexidine rinses after meals.

Clinical assessments, including pain, bleeding, wound cleanliness, and healing progression, are recorded at multiple time points up to 30 days. Radiographic evaluation of bone density is performed at 30, 60, and 90 days using cone beam computed tomography.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Radiographic bone density measured using cone beam computed tomography at 90 days post-extraction

Key secondary outcome(s)

1. Postoperative pain measured using visual analogue scale ranging from no pain to worst imaginable pain at 3, 7, and 15 days post-extraction

2. Postoperative bleeding measured using clinical assessment of presence or absence of bleeding at 24 and 72 hours post-extraction

3. Mucosal healing time measured using the number of days to complete epithelialization of the extraction socket at up to 30 days post-extraction

Completion date
10/06/2026

Eligibility

Key inclusion criteria
1. Adult non-smoking patients selected randomly
2. Patients in apparently good health and not undergoing any pharmacological therapy
3. Patients requiring simple extractions defined as non-surgical (extractions without flap elevation or ostectomy), bilaterally involving similar elements (teeth with comparable characteristics that, after extraction, result in overlapping bone defects) due to severe caries or fractures
4. Extractions performed in the same session to allow appropriate evaluation of radiological data over time

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
46

Key exclusion criteria
1. Patients who did not comply with the follow-up protocol described in the subsequent chapters
2. Patients with active periodontal disease

Date of first enrolment
02/01/2023

Date of final enrolment

30/09/2025

Locations

Countries of recruitment
Italy

Sponsor information

Organisation
University of Bari Aldo Moro

ROR
https://ror.org/027ynra39

Funder(s)

Funder type

Funder Name
Universita degli Studi di Bari Aldo Moro

Alternative Name(s)
University of Bari Aldo Moro

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available