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3D-printable biopolymers and their use in dentistry

Submission date	Recruitment status	[_] Prospectively registered
02/03/2024	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/03/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/03/2024	Oral Health	[_] Record updated in last year

Plain English summary of protocol
All the patients enrolled in the study had a financial convenience , since .
The study was conducted in and lasted from June 2023 to July 2023.
No funds were received for the trial and the responsible was the adjunct professor

Background and study aims
The goal of this clinical study is to assess how well 3D printed biopolymers, mixed with materials that promote bone growth (beta-tricalcium phosphate and hydroxyapatite), work for closing soft tissues after having a tooth removed.

Who can participate?
The study was opened to all patients requiring a tooth extraction

What does the study involve?
The procedure involved removing the tooth, and then randomly choosing whether to close the socket using a 3D printed disk made from two types of biodegradable materials: polylactic acid and polycaprolactone. Both materials were mixed with synthetic ceramic substances that promote bone growth, specifically 10% hydroxyapatite and 20% beta tricalcium phosphate, respectively.

What are the possible benefits and risks of participating?
The procedure was done free of charge.
No risks

Where is the study run from?
Trisakti University (Indonesia)

When is the study starting and how long is it expected to run for?
May 2023 to July 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Nicola De Angelis, n.deangelis74@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Nicola De Angelis

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
3D-printable biopolymers for socket preservation technique: soft tissues response. A randomized clinical trial.

Study objectives
Soft tissues response after tooth extraction is the same whether the socket is sealed by a polymeric 3D printed disk or is left open to heal

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 03/05/2023, Ethics Committee for Health Research Faculty of Dentistry, Universitas Trisakti (Jl. Kyai Tapa No.260 4, RT.4/RW.16, Jakarta, 11440, Indonesia; +62 21 566 3232; komisietikfkg@trisakti.ac.id), ref: 641/S3/KEPK/FKG/5/2023

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic

Study type(s)
Treatment

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied
Soft tissues response following teeth extractions

Interventions
All the extractions were performed without flap elevation without any antibiotic prophylaxis. A careful cleaning of the socket was done in order to exclude the possible presence of inflammatory tissue, without grafting any additional bone substitute. Once tooth extraction was completed, the operator opened a sealed envelope containing the result of the randomization in order to include the patient in one of the following study groups:

TEST 1: a 3D printed disk of poli-D-lactic acid with 10% of hydroxyapatite had to be trimmed inside the gingival margin and ensured with a crossed mattress suture.

TEST 2: a 3D printed disk of poli- ε caprolactone with 20% of β-tricalcium phosphate had to be trimmed inside the gingival margin and ensured with a crossed mattress suture.

CONTROL: extraction left to heal without any graft materials. Only a collagen sponge was used in case of excessive bleeding.

Intervention Type
Procedure/Surgery

Primary outcome measure
Soft tissues closure was measured at the baseline and 30 days after the procedure with intraoral photographs

Secondary outcome measures
Bone formation was measured at the baseline at 30 days after the procedure with intra-oral periapical X-rays

Overall study start date
03/05/2023

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Medically healthy
2. No assumption of bifosphonates
3. No or light – medium smokers (maximum 10 cigarettes/day)
4. Requiring a tooth extraction

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
39

Total final enrolment
39

Key exclusion criteria
1. Pregnancy and lactation
2. Patients with signs of acute infection at the extraction site

Date of first enrolment
01/06/2023

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
Indonesia

Study participating centre
Trisakti University Dental Department
Jakarta
Indonesia
11440

Sponsor information

Organisation
Trisakti University

Sponsor details
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Sponsor type
University/education

Website
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ROR
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Organisation
University of Genoa

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Sponsor type
University/education

Website

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ROR
https://ror.org/0107c5v14

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal

Intention to publish date
30/03/2024

Individual participant data (IPD) sharing plan
The datasets generated during the study will be amiable upon request from Nicola De Angelis n. deangelis74@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			04/03/2024	No	Yes
Protocol file	version 1		04/03/2024	No	No