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Piezoelectric drills for dental implants

Submission date	Recruitment status	[_] Prospectively registered
08/04/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/04/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/09/2024	Oral Health	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Traditional dental implant site preparation methods pose challenges including tissue damage and compromised appearance. Piezosurgery offers a minimally invasive alternative, but its effectiveness is underexplored. This study aims to compare piezosurgery and conventional surgery for dental implant site preparation, focusing on bone density, implant stability, and bone loss.

Who can participate?
Patients aged 18-50 years who are missing at least two teeth, at least one of which is in the back region of the lower jaw

What does the study involve?
Patients are treated sequentially at the two sites where they are missing teeth: at one site implant placement is conducted using piezoelectric surgery and at the other site conventional surgery is used. Post-surgical evaluations were conducted at 6 and 9 months.

What are the possible benefits and risks of participating?
Participants may benefit from receiving dental implants. Possible risks are post-operative complications including pain and swelling.

Where is the study run from?
Army Hospital Research and Referral (India)

When is the study starting and how long is it expected to run for?
December 2016 to October 2023

Who is funding the study?
Army Hospital Research and Referral (India)

Who is the main contact?
Manish Rathi, manishrathi.077h@gov.in

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
16CNAHMMDS000002

Study information

Scientific Title
Comparative evaluation of piezosurgery versus conventional surgery in dental implants

Study objectives
Implant sites prepared with piezoelectric drills are better in terms of implant stability, bone density around implants and patient post-operative recovery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/09/2016, Army Dental Centre (R&R) Institutional Committee (Dhaula Kuan, New Delhi, 110010, India; +91 (0)9862157110; dental.oc86-ar@gov.in), ref: 16CNAHMMDS000002

Study design
Single-centre split-mouth interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic, University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Dental implant

Interventions
Thirty patients with two edentulous sites, at least one of which was in the posterior mandibular region, were treated sequentially at two sites: Site A, where implant placement was conducted using piezoelectric surgery, and Site B, where conventional surgery was employed. Post-surgical evaluations were conducted at 6 and 9 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Bone density measured using dual-energy x-ray absorptiometry (DEXA) scan at baseline, 6 and 9 months
2. Implant stability measured using resonance frequency analysis (RFA) scan at baseline and 6 months

Secondary outcome measures
Patient’s perception of surgery by measuring postoperative pain using a visual analogue scale (VAS) at 7 days postoperative

Overall study start date
25/12/2016

Completion date
31/10/2023

Eligibility

Key inclusion criteria
1. Aged 18 - 50 years
2. Edentulous site in posterior mandibular region
3. Availability of adequate bone volume without any surgical modification

Participant type(s)
Patient

Age group
Other

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. H/o extraction <6 months prior to placement of implant
2. Immunocompromised individual
3. Previous irradiation treatment in head and neck area
4. H/o periodontal disease (active/treated)
5. H/o bone metabolic disorders

Date of first enrolment
16/12/2016

Date of final enrolment
26/01/2022

Locations

Countries of recruitment
India

Study participating centre
ADC (R&R)
Dhaula Kuan
New Delhi
India
110010

Sponsor information

Organisation
Army Hospital Research and Referral

Sponsor details
Dhaula Kuan
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04zh7mt66

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Army Hospital Research and Referral

Results and Publications

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

Intention to publish date
01/08/2024

Individual participant data (IPD) sharing plan
Data is saved in a non-publically available repository: the institutional repository of the University of Delhi.
The type of data stored: tables, figures, photographs.
The process for requesting access (if non-publicly available): contact the corresponding author Manish Rathi (manishrathi.077h@gov.in).

IPD sharing plan summary
Stored in non-publicly available repository