Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of X-ray in CBCT imaging on the rate of nuclear changes and Repair Index of buccal mucosal cells

Protocol summary

Study aim

Determining the effect of X-ray exposure in CBCT imaging on nuclear changes and buccal mucosal cell repair in patients referred to the Department of Oral and Maxillofacial Radiology, Tehran Azad University in 1401

Design

Clinical trial without a control group, phase 2 on 60 patients to evaluate the effect before and after

Settings and conduct

The buccal mucosal cells are shaved with a damp spatula from the buccal mucosa adjacent to the imaging site, and these cells are spread on clean slide glass slides. Slides are allowed to air dry at room temperature. After sampling, CBCT is prepared for patients. CBCT images will be provided. The sample will be taken immediately before exposure and 10 days after imaging. Papanicolaou staining is then used to measure micronuclei and other nuclear changes, and observation will be performed with a light microscope.

Participants/Inclusion and exclusion criteria

Adults 18 to 45 years of age who have not had radiotherapy in the past 28 days, do not use cigarettes or mouthwash containing alcohol, are not currently receiving medical treatment, and not taking medications such as immunosuppressants, anti-inflammatory drugs, corticosteroids, antivirals, etc. Patients must not have systemic diseases that affect the oral mucosa, such as viral diseases, lichen planus, pemphigus, Sjogren's syndrome, Reiter, Behcet, lupus, scleroderma, etc.

Intervention groups

X-ray produced during CBCT imaging

Main outcome variables

Specific target variables 1: Micronucleus, Karyorrhexis, Karyolysis, Broken egg, Repair index before radiation exposure in CBCT imaging by sex and FOV Specific target variables 2: Micronucleus, Karyorrhexis, Karyolysis, Broken egg, and Repair Index after exposure to radiation in CBCT imaging by sex and FOV

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220418054582N1**
Registration date: **2022-05-30, 1401/03/09**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-30, 1401/03/09**
Update count: **0**

Registration date

2022-05-30, 1401/03/09

Registrant information

Name

parissa shahmohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 4573

Email address

parissashahmohammadi91@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of X-ray in CBCT imaging on the rate of nuclear changes and Repair Index of buccal mucosal cells

Public title
Evaluation of the effect of X-ray in CBCT imaging on the rate of nuclear changes and Repair Index of buccal mucosal cells
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adults 18 to 45 years old who have come to the university for a CBCT scan.
Exclusion criteria:
Perform radiotherapy in the last 28 days Smoking and mouthwash containing alcohol Existence of systemic disease Taking effective drugs in the oral mucosa
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **2**
before and after
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University of Tehran
Street address
No 9, 9th Neyestan, Pasdaran Ave
City
Tehran
Province
Tehran
Postal code
1946853314

Approval date
2022-04-13, 1401/01/24
Ethics committee reference number
IR.IAU.DENTAL.REC.1401.007

Health conditions studied

1

Description of health condition studied
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The extent of micronucleus changes after X-ray exposure in CBCT imaging
Timepoint
At the beginning of the study (before exposure) and 10 days after exposure
Method of measurement
Observation with a light microscope

2

Description
The extent of Karyorrhexis changes after X-ray exposure in CBCT imaging
Timepoint
At the beginning of the study (before exposure) and 10 days after exposure
Method of measurement
Observation with a light microscope

3

Description
The extent of Karyolysis changes after X-ray exposure in CBCT imaging
Timepoint
At the beginning of the study (before exposure) and 10 days after exposure
Method of measurement
Observation with a light microscope

4

Description
The extent of Broken egg changes after X-ray exposure in CBCT imaging
Timepoint
At the beginning of the study (before exposure) and 10 days after exposure
Method of measurement
Observation with a light microscope

5

Description

The extent of Repair Index changes after X-ray exposure in CBCT imaging

Timepoint

At the beginning of the study (before exposure) and 10 days after exposure

Method of measurement

Calculate according to the formula

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: X-ray exposure

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Oral and Maxillofacial Radiology, Islamic Azad University of Tehran

Full name of responsible person

Parissa Shahmohammadi

Street address

No 9, 9th Neyestanm, Pasdaran Ave

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parissashahmohammadi91@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ahmadreza Talaipour

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ar_talai@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Parissa Shahmohammadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Islamic Azad University

Full name of responsible person

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Resident

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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available