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Effects of reducing the parameters on dental x-ray machine on image quality and cell toxicity

Submission date	Recruitment status	[_] Prospectively registered
30/04/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/05/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/06/2021	Oral Health	

Plain English summary of protocol

Background and study aims
A dental x-ray is essential to aid diagnosis and treatment planning. It is important to give clinicians information that cannot be obtained through physical examination. The increased use of x-rays increases radiation exposure. This has raised concern as exposure to radiation can cause cell damage and alterations which can increase the risk of developing oral cancer. One of the ways to reduce radiation exposure is by reducing the parameters available on the x-ray machine which are tube potential (kV) and tube current (mA). Although it is ideal and easy to reduce the parameters, the value and quality of the images must not be compromised. Thus, the aim of this study is to study the effect of reducing x-ray parameters on the diagnostic value and quality of the images. This study also looks at the presence of nuclear alterations after exposure to dental x-rays when the radiation dose is reduced.

Who can participate?
Patients aged 18 - 35 who attend the orthodontic clinic and were indicated for DPT and LC as part of routine assessment before starting orthodontic treatment

What does the study involve?
Patients are randomly allocated into two groups, control and intervention. The control group receive a standard radiation dose by setting x-rays machine in auto-mode. The intervention group receive a reduced radiation dose by decreasing the parameters on the x-ray machine. A buccal mucosa (the inner lining of the lips and cheeks) smear is taken using a brush and participants have a routine orthodontic assessment. Participants are then sent for a dental x-ray. They are called back to the clinic 10 days after the x-rays for a second buccal mucosa smear.

What are the possible benefits and risks of participating?
The participants in the intervention group may benefit from receiving a lower radiation dose. The risks include slight discomfort when the buccal mucosa smear is taken.

Where is the study run from?
Universiti Teknologi MARA (Malaysia)

When is the study starting and how long is it expected to run for?
March 2017 to August 2019

Who is funding the study?
Universiti Teknologi MARA (Malaysia)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
600-IRMI (5/1/6)

Study information

Scientific Title
Effects of scanning parameters reduction in dental radiographs on quality and diagnostics performance of the images and cytotoxicity of nuclei

Study objectives

1. There is no difference in image quality and diagnostic performance between standard and reduced scanning parameters.
2. There is a reduction in nuclei cytotoxicity when scanning parameters is reduced.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/07/2017, Uitm Research Ethics Committee (Universiti Teknologi MARA, Aras 3, Bangunan Wawasan, 40450 Shah Alam, Selangor, Malaysia; +60 (0)355448069; recsecretariat@uitm.edu.my), ref: REC/232/17

Study design
Single-centre double-blind parallel-group trial randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Digital dental panoramic tomogram and lateral cephalogram radiation exposure

Interventions
Participants were randomized 1:1 into control and intervention groups. The control group received standard scanning parameters as prescribed by the manufacturer by setting the radiographic machine in auto mode. Participants in the intervention group received reduced scanning parameters where the dental panoramic tomogram (DPT) was reduced by 60% and lateral cephalogram (LC) by 30%. All the participants were exposed to radiation once for each modality. Buccal mucosa smears were taken before radiation exposure and 10 days after the radiation exposure.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure

1. Diagnostic performance of the images assessed using detection of anatomical landmarks (25 landmarks on dental panoramic tomogram and 35 landmarks on lateral cephalogram) after the x-rays were taken
2. The presence of nuclear alterations (pyknosis, karyolysis, karyorrhexis and nuclear budding) of buccal mucosa smear was noted (yes/no), taken before the exposure to x-rays and 10 days after the x-rays

Secondary outcome measures
Quality of the images assessed using a five-point rating scale after the x-rays taken (1= excellent, 2= more than adequately presented, 3= adequately presented 4= barely adequately presented, 5= inadequately presented)

Overall study start date
01/03/2017

Completion date
31/08/2019

Eligibility

Key inclusion criteria
1. Adults 18-35 years old
2. Indicated for dental panoramic tomogram and lateral cephalogram
3. Fit and healthy
4. Normal body mass index (BMI) 18.5 - 25

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Both

Target number of participants
38

Total final enrolment
38

Key exclusion criteria
1. Patients contraindicated for radiographic examination
2. Pregnant

3. Occupational health exposure
4. Facial and skeletal abnormalities
5. Bone disease
6. Smoking or has stopped less than 6 months
7. Oral diseases including ulcers in the past 2 weeks

Date of first enrolment
01/02/2018

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
Malaysia

Study participating centre
Universiti Teknologi MARA
Orthodontic Clinic
Faculty of Dentistry
Kampus Sungai Buloh
Jalan Hospital
Sungai Buloh
Malaysia
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Sponsor information

Organisation
Universiti Teknologi MARA

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Faculty of Dentistry
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Sponsor type
University/education

Website

http://www.uitm.edu.my/index.php/en

ROR
https://ror.org/05n8tts92

Funder(s)

Funder type
University/education

Funder Name
Universiti Teknologi MARA

Results and Publications

Publication and dissemination plan
The plan for this study is to divide the trial into two parts (two publications) where the first part will report the results regarding diagnostic performance and quality of the images. The second part will report the score of nuclei alterations of the buccal mucosa.

Intention to publish date
01/11/2020

Individual participant data (IPD) sharing plan
For this study, the participants' level data are the x-ray images (DPT and LC) and slides containing buccal mucosa smears. All images are stored online on UiTM's Integrated Dental Records Management System (iDERMS) (https://dentistry.uitm.edu.my/v2/index.php/en/) and can only be assessed by clinician in-charged using UiTM's intranet system. X-rays and any patients' records are medico-legal documents thus the access is restricted. Prior to the commencement of the study, informed consent was obtained from patients.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2021	24/06/2021	Yes	No