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The use of a laser and pilocarpine in improving saliva secretion in patients with head and neck cancer who have undergone radiochemotherapy

Submission date
07/08/2023

Recruitment status
No longer recruiting

Registration date
21/08/2023

Overall study status
Completed

Last Edited
21/08/2023

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This is an interventional study aimed at enhancing oral health and minimizing the potential complications associated with radiochemotherapy. The study will be conducted at the Faculty of Dentistry, Damascus University, and the Al-Biruni Cardiac Surgery Hospital Department. The goal is to alleviate discomfort and minimize the impact of radiochemotherapy on salivary gland function, ultimately improving your overall well-being during this critical treatment phase.

Who can participate?
Patients aged 18 years old or over undergoing radiochemotherapy

What does the study involve?
Participants will undergo a comprehensive clinical examination before radiochemotherapy, ensuring any existing oral conditions are treated to minimize potential complications. Instructions for oral hygiene maintenance will be provided, including avoiding certain foods and drinks that could exacerbate oral discomfort.

Intervention Groups:
Participants will be randomly assigned to one of three groups:

Group I: Pilocarpine Hydrochloride (Salagen) Group
Participants in this group will receive Pilocarpine hydrochloride tablets three times a day, an hour before meals, from the first radiochemotherapy session until the end of treatment.

Group II: Laser Group
Participants in this group will undergo Diode Laser treatment three times a week, starting from the first radiochemotherapy session and continuing until the end of treatment. The laser application will target major and small salivary glands, following a predetermined protocol.

Group III: Combined Laser and Pilocarpine Hydrochloride Group
Participants in this group will receive both Pilocarpine hydrochloride tablets and Diode Laser

treatment, beginning with the first radiochemotherapy session and ending with the final treatment.

Saliva samples will be collected using a standardized protocol. Unstimulated saliva samples will be collected by asking participants to collect saliva in the floor of their mouth every 5 minutes for 15 minutes. Stimulated saliva samples will be collected after chewing sugar-free gum. These samples will help us assess the effectiveness of the interventions on saliva secretion.

What are the possible benefits and risks of participating?
By participating in this study, you contribute to advancements in oral health care during radiochemotherapy. Moreover, you will receive enhanced oral care and attention throughout your treatment journey, potentially reducing discomfort and enhancing your overall quality of life. There are no possible risks of participating except failure to benefit from the treatment provided, failure to alleviate the oral side effects of chemo-radiotherapy, and failure to improve the quality of patients' life.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
April 2022 to July 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Ms Aya Dawoud Agha, aya.dagha96@damascusuniversity.edu.sy

Contact information

Type(s)
Scientific

Contact name
Ms Aya Dawoud Agha

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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
The synergistic effect of low-level laser and pilocarpine hydrochloride on saliva in patients with head and neck cancer who receive radiochemotherapy: Clinical randomized controlled study

Study objectives
H0: (null hypothesis) There is no statically significant difference between groups in the study variables in patients with cancer who receive radiochemotherapy.
H1: (alternative hypothesis) There is a statically significant difference between groups in the study variables in patients with cancer who receive radiochemotherapy.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/06/2022, Damascus University (Department of Oral Medicine Mazza High Way, Damascus, 0000, Syria; 00963991545550; info@damascusuniversity.edu.sy), ref: 2390sm

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Hospital, Medical and other records

Study type(s)
Prevention, Quality of life, Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Patients with head and neck cancer and radiochemotherapy

Interventions

Study Design and Purpose:
This study employs a randomized controlled trial design to evaluate the effectiveness of different interventions in maintaining oral health during radiochemotherapy. The goal is to alleviate discomfort and minimize the impact of radiochemotherapy on salivary gland function, ultimately improving your overall well-being during this critical treatment phase.

Intervention Groups:
Participants will be randomly assigned using Research Randomizer (https://www.randomizer.org) to one of three groups:

Group I: Pilocarpine Hydrochloride (Salagen) Group

Participants in this group will receive Pilocarpine hydrochloride tablets three times a day, an hour before meals, from the first radiochemotherapy session until the end of treatment.

Group II: Laser Group

Participants in this group will undergo Diode Laser treatment three times a week, starting from the first radiochemotherapy session and continuing until the end of treatment. The laser application will target major and small salivary glands, following a predetermined protocol.

Application of diode laser using contact mood and continuous waves on:
The major salivary glands with a wavelength of 810 nm, a power of 0.4 w, a duration of 17.5 s, a spot size of 2, 54 cm2 and each point receives 7 J.
The small salivary glands with a wavelength of 650 nm, a power of 40 MW, a duration of 7 s, a spot size of 0, 5 cm2 and each point receives 0.28 J.

Group III: Combined Laser and Pilocarpine Hydrochloride Group

Participants in this group will receive both Pilocarpine hydrochloride tablets and Diode Laser treatment, beginning with the first radiochemotherapy session and ending with the final treatment.

Study Procedures:
Participants will undergo a comprehensive clinical examination before radiochemotherapy, ensuring any existing oral conditions are treated to minimize potential complications.
Instructions for oral hygiene maintenance will be provided, including avoiding certain foods and drinks that could exacerbate oral discomfort.

Saliva Collection:
Saliva samples will be collected using a standardized protocol. Unstimulated saliva samples will be collected by asking participants to collect saliva on the floor of their mouth every 5 minutes for 15 minutes. Stimulated saliva samples will be collected after chewing sugar-free gum. These samples will be used to assess the effectiveness of the interventions on saliva secretion.

Intervention Type

Device

Pharmaceutical study type(s)

Bioequivalence

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Pilocarpine hydrochloride, Diode laser

Primary outcome measure
Volume of saliva secretion measured by weighing collected saliva samples on an accurate scale and subtracting the weight of the used tube from the obtained result in periods R1/R2/R3. (R: radiotherapy phase)

R1: when a patient receives their first radiochemotherapy session
R2: when a patient receives their last radiochemotherapy session
R3: after 3 months of ending the radiochemotherapy sessions

Secondary outcome measures
Saliva pH measured using standard laboratory kits designed for this function in the periods R1 /R2/R3.
(R: radiotherapy phase)

R1: when a patient receives their first radiochemotherapy session
R2: when a patient receives their last radiochemotherapy session
R3: after 3 months of ending the radiochemotherapy sessions

Overall study start date
21/04/2022

Completion date
01/07/2024

Eligibility

Key inclusion criteria
1. The minimum radiation dose to which the patient is exposed is 50 Gy
2. Radiation should be at least above the parotid gland and the submandibular gland on both sides
3. The patients are 18 years old or over
4. The patients did not undergo radiotherapy before
5. The patients did not undergo chemotherapy for at least the past two months
6. Karnofsky performance scale above 60

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
24

Total final enrolment
24

Key exclusion criteria
1. Sjogren's syndrome, diabetes and autoimmune diseases
2. Clinically significant uncontrolled cardiac, renal, pulmonary, visual problems or other chronic diseases that could potentially interfere with the evaluation of the safety and efficacy of pilocarpine
3. Tricyclic antidepressants, antihistamines with anticholinergic effects or Beta-blockers
4. Pilocarpine for ophthalmic indications was also excluded from the study
5. Tumor located in the parotid gland, submandibular gland, the blood or the floor of the mouth

Date of first enrolment
22/06/2022

Date of final enrolment
01/03/2024

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Department of Oral Medicine
Mazza High Way
Damascus
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0000

Sponsor information

Organisation
Damascus University

Sponsor details
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Sponsor type
University/education

Website
http://damasuniv.edu.sy/

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

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

Intention to publish date
31/07/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Mrs Aya Dawoud Agha, aya.dagha96@damascusuniversity.edu.sy (Syria)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			17/08/2023	No	Yes