Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparision of a newly developed laser pen as a home care device versus conventional treatment in reduction of gingival inflammation reduction and acceleration of aphthous and herpetic lesion in up to 15 years old population

Protocol summary

Summary

The aim of this study is to determiningofthe effect of laser tooth brush and also aphthous and herpetic laser pens in reduction of gingival inflammation after doing of conventional treatment and determining of the laser pen effect in reduction of pain and acceleration of wound healing in the patient with aphthous or herpetic lesion. inclusion criteria including gingivitis and chronic periodontitis in laser tooth brush group and minor aphthous laesion in the aphthous laser pen group and also the patient with herpetic lesion (in the three stages:premordial,vesicle,crust).exclusion criteria including:malignancy,thyroid ptoblem,pregnancy,phtosensitivity,epilepsy and mental retardations).this study will be done in the population up to 15 years old after disease diagnosis and fulfilment of patient's consent form and also education of the devices usage. the main outcoms including pain reduction, healing time, bleeding index, gingival index and gingival pocket index will be measured after starting of intervention and during three months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013061113639N1**
Registration date: **2013-07-29, 1392/05/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-07-29, 1392/05/07

Registrant information

Name
Masoud Shabani
Name of organization / entity
Ardebi University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Deputy For Research of Ardebil University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2014-03-19, 1392/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of a newly developed laser pen as a home care device versus conventional treatment in reduction of gingival inflammation reduction and acceleration of aphthous and herpetic lesion in up to 15 years old population

Public title

Construction of laser tooth brush ,laser aphthous pen and laser herpetic ulcer pen for improving of gum

healthy and mouth wounds

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:up to 15 years old; fulfilment of consent form; suffer from gingivitis and periodontitis; herpetic ulcer and aphthous ulcer exclusion criteria: pregnancy; malignancy; photosensitivity; thyroid problems; mental handicap; coagulopathy; corticosteroid application; epilepsy

Age

From **15 years** old to **149 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

research ethical committee of ardebil university of medical sciences

Street address

ardebil university of medical sciences

City

ardebil

Postal code

0451-5522196

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

arums.rec.1391.23

Health conditions studied

1

Description of health condition studied

periodontitis,aphthous ulcer,herpetic ulcer

ICD-10 code

k00-k14

ICD-10 code description

Diseases of oral cavity, salivary glands and jaws,Other viral diseases

Primary outcomes

1

Description

dental microbial plaque index

Timepoint

weekly and monthly

Method of measurement

disclosing agent and periodontal probe and observation

2

Description

periodontal pocket index

Timepoint

monthly

Method of measurement

periodontal probe

3

Description

gingival bleeding index

Timepoint

weekly and monthly

Method of measurement

periodontal pocket probe and observation

4

Description

gingival index

Timepoint

monthly

Method of measurement

periodontal probe and observation

5

Description

visual analogue scale(VAS)

Timepoint

befor intervention,immediately,daily,

Method of measurement

interview and standard cheklist

6

Description

function activity

Timepoint

daily

Method of measurement

interview and standard check list

7

Description
ulcer recurrent activity
Timepoint
monthly
Method of measurement
interview and standard check list

8

Description
time of cure
Timepoint
daily weekly monthly and annually
Method of measurement
interview and check list

Secondary outcomes

empty

Intervention groups

1

Description
intervention lased group:The group one (n = 10) is treated with 660 nm, 40 mW, continuous wave, 566 mw/cm2, class 2M, for five consecutive days (twice per day, 30 seconds each session).
Category
Treatment - Devices

2

Description
intervention group one (lased grouo):a laser tooth brush with wavelength 660nm, output power 40mw,spot size 3mm, power density 566mw/cm2,irradiation time 10 seconds energy, density5.66 J/cm2, laser tooth brush was perpendicularly applied during laser emission at the labial (buccal) interdental papilla ,every other two days. This method is applied by patient at home, after receiving the face to face education and after getting the best skill training at the office in order to use it at home by wearing eye glasses protector.
Category
Treatment - Devices

3

Description
intervention lased group:The group one (n = 10) is treated with 655 nm, 40 mW, continuous wave, 655mw/cm2, class 2M, 30 seconds . this intervention is implemented for herpetic lesion in prodromal and vesicular stages but in the crust stage the laser setting will be the power of 40mw and 120 second irradiation time .
Category
Treatment - Devices

4

Description
in the first control group for aphthous ulcer we will use non laser red light as placebo ,two times per day for 30seconds for 5 days
Category
Treatment - Drugs

5

Description
inthe first control group for herpetic lesion we will use the nonlaser red light as placebo for30seconds in the primordial and vesicle stage and also for 120 seconds in the crust stage in one week
Category
Treatment - Drugs

6

Description
in the second control group for aphthous ulcer we will use the adcortyl in orabase ointment,4 times per day for 5 days
Category
Treatment - Drugs

7

Description
in thefirst control group for reduction of the gingival inflammation we will use the nonlaser red lihgt as placebo ,two times per day at the interdental papilla
Category
Treatment - Drugs

8

Description
in the second control group for reduction of the gingival inflammation reduction we will use the tooth brush plus tooth paste two times per day
Category
Treatment - Drugs

9

Description
in the second control group for herpetic lesion we will use the acyclovir ointment in the primordial and vesicle stage four times per day in oneweek
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental And Dermatological Clinics
Full name of responsible person

Masoud shabani And Hassan Adalatkhah

Street address

Sarcheshmeh Square

City

Ardebil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy For Research

Full name of responsible person

Dr.Haddi Piriee

Street address

Ardebil University of Medical Sciences

City

Ardebil

Grant name

10506000متمرکز و ردیف جاری و10503000

Grant code / Reference number

10506000،10503000

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

Yes

Title of funding source

Deputy For Research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ardebil University of Medical Sciences

Full name of responsible person

Masoud Shabani

Position

Head of Oral Health -School Health-Health Education Department DDS,Msc laserdontics

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty