Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of mouthwash containing mulberry (Morus nigra L.) fruit juice for treatment of gingivitis

Protocol summary

Summary

The aim of this study is evaluation of the effect of mulberry fruit juice for treatment of gingivitis.This study is a randomized double blind clinical trial on 60 patients with acute gingivitis. The selected people are non-smokers and without any systemic disease. The patients divided into 3 groups; Group 1: mulberry juice mouthwash, Group 2: chlorhexidine mouthwash and Group3: normal saline mouthwash. All the patients are instructed to use 10 ml of the mouthwash twice daily (morning and evening) after brushing and flossing. Plaque and gingival indices in the first visit and then at 1 and 2 months after the beginning of treatment are evaluated and analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091329802N1**
Registration date: **2016-10-09, 1395/07/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-10-09, 1395/07/18

Registrant information

Name

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Name of organization / entity

Mazandaran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Research and Technology Deputy, Mazandaran University of Medical Sciences

Expected recruitment start date

2016-06-29, 1395/04/09

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of mouthwash containing mulberry (Morus nigra L.) fruit juice for treatment of gingivitis

Public title

Effect of mouthwash containing mulberry for treatment of gingivitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with gingivitis; probing depth 4 mm or less; having at least 24 teeth excluding third molar; Absence of any active carious lesion; bleeding on probing. Exclusion criteria: smokers; using any antibiotics during the last 3 months; presence of any systemic diseases; pregnancy.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Mazandaran University of Medical Sciences

Street address

Deputy of Research and Technology, Moallem Square

City

Sari

Postal code

Approval date

2016-06-28, 1395/04/08

Ethics committee reference number

IR.MAZUMS.REC.95.2078

Health conditions studied

1

Description of health condition studied

Gingivitis

ICD-10 code

K05.0

ICD-10 code description

Acute gingivitis

Primary outcomes

1

Description

Gingival Index

Timepoint

In the first visit and then at 1 and 2 months after the beginning of treatment

Method of measurement

Observation and evaluation

Secondary outcomes

1

Description

Plaque Index

Timepoint

In the first visit and then at 1 and 2 months after the beginning of treatment

Method of measurement

Observation and evaluation

Intervention groups

1

Description

Intervention 1: mulberry 1% mouthwash, twice daily for 2 month, 10 ml every time

Category

Treatment - Drugs

2

Description

Intervention 2 : Chlorhexidine 0.2% mouthwash, twice daily for 2 months, 10 ml every time

Category

Treatment - Drugs

3

Description

intervention 3 : Normal saline mouthwash, twice daily for two months, 10 ml every time

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Maedeh Salehi

Street address

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research and Technology Deputy, Mazandaran University of Medical Sciences

Full name of responsible person

Dr Ahmad-Ali Enayati

Street address
Research and Technology Deputy, Moallem square
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research and Technology Deputy, Mazandaran University of Medical Sciences
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

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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