

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Clinical evaluation of the effect of Nanohydroxyapatite on White Spot lesions in orthodontic patient

Protocol summary

Study aim

Evaluation of the effect of Nano-hydroxyapatite on White Spot lesions in orthodontic patient

Design

In this study, 25 participant will receive toothpastes contain nano-hydroxyapatite and 25 person will receive non-nano-hydroxyapatite toothpastes. They should be taken twice daily for 6 months.

Settings and conduct

This study will be conducted at the orthodontics department of Shahid Beheshti Dental School and with the consent of the participants

Participants/Inclusion and exclusion criteria

The orthodontic treatment will be finished: bad oral hygiene

Intervention groups

The participants will be given a toothpaste to use for six months, either with or without a nano-hydroxyapatite that is randomly selected.

Main outcome variables

Tooth remineralization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180928041162N1**

Registration date: **2018-11-10, 1397/08/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-10, 1397/08/19**

Update count: **0**

Registration date

2018-11-10, 1397/08/19

Registrant information

Name

Nima Jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4422 2717

Email address

nima_igt@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-28, 1396/12/09

Expected recruitment end date

2018-12-30, 1397/10/09

Actual recruitment start date

2018-08-09, 1397/05/18

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of the effect of Nanohydroxyapatite on White Spot lesions in orthodontic patient

Public title

Evaluation of the effect of Nanohydroxyapatite on White Spot lesions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Finishing the orthodontic treatment Compliance with oral hygiene

Exclusion criteria:

Bad oral hygiene

Age

No age limit

Gender

Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **50**
Actual sample size reached: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants are divided to two group and each group receive one tothpaste that is blind to us belongs to that group

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study nobody knows about wich tothpaste is the main tothpaste and that is the usuall tothpaste except manufacturing factory

Placebo
Not used

Assignment
Parallel

Other design features
.....

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Velenjac.daneshjo blv

City
tehran

Province
Tehran

Postal code
1983963113

Approval date
2017-07-31, 1396/05/09

Ethics committee reference number
IR.SBMU.RIDS.REC.1396.485

2

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address

Velenjac.daneshjo blv

City
TEHRAN

Province
Tehran

Postal code
1983963113

Approval date
2017-07-31, 1396/05/09

Ethics committee reference number
IR.SBMU.RIDS.REC.1396.485

Health conditions studied

1

Description of health condition studied
Whitespot lesion

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Enamel remineralizasion

Timepoint
0-1-3-6 month after using tothpaste

Method of measurement
Diagnodent:photography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: using tothpaste for 6 month

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid beheshti orthodontic department

Full name of responsible person
Asghar ebadifar

Street address
Velenjac ,daneshjo blv

City
Tehran

Province
Tehran

Postal code

4371733661

Phone

+98 13 4422 2717

Email

nima_igt@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

اصغر عبادی فر

Street address

VELENJAC.DANESHJO BLV

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Email

NIMA_IGT@YAHOO.COM

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

10

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

2

Sponsor

Name of organization / entity

Shahid beheshti dentofacial deformities reserch center

Full name of responsible person

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Phone

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Email

Reserch.ids@sbmu.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid beheshti dentofacial deformities reserch center

Proportion provided by this source

90

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Asghar ebadifar

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Province

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Phone

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Email

Nima_igt@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Asghar ebadifar

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry
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Email
Nima_igt@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Nima jafari
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
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Postal code
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Phone
+98 13 4422 2717
Email

Nima_igt@yahoo.com

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

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

A portion of the data that does not contain the personal information of the participants will be published

When the data will become available and for how long

Release of the data will be one year after print the results

To whom data/document is available

Researchers and industry workers can use this study

Under which criteria data/document could be used

It is safe to use this data with mention the source of the this information

From where data/document is obtainable

Asghar ebadifar0 tehran velenjak daneshjo blv.
orthodontic department of shahid beheshti dental school
1983963113 tel:02122403075

What processes are involved for a request to access data/document

One month after receive the request

Comments