Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 recieve toothpastes contain nano-hydroxyapatite and 25 person will recive 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 finish exit: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
Toth 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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+98 21 2240 3075

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
Asghar ebadi far

Street address
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tehran

Province
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+98 21 2241 3897

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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Daneshjo blv

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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
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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
Dentistry

Street address
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Tehran

Province
Tehran

Postal code
1983963113

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