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
City
TEHRAN
Province
Tehran
Postal code
1983963113
Phone
+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
Velenjac. daneshjo blv
City
tehran
Province
Tehran
Postal code
1983963113
Phone
+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
Street address
Daneshjo blv
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2240 3075
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

Street address

Daneshjo blv

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2242 3075

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

Dentistry

Street address

Daneshjo blv

City

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