

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Oral health related quality of life and comparison between preventive regimens among Iraqi preadolescents

Protocol summary

Study aim

1. To examine oral health related quality of life among 8-10 year old schoolchildren in the Wasit Governorate-Iraq.
2. To assess the efficacy and the cost of preventive regimens used in both intensified and basic intervention groups.

Design

Controlled randomized Clinical trial with parallel groups, phase 2 on 372 participants, single center

Settings and conduct

Children from two schools (one boy school and one girl school randomly selected) will be allocated into basic intervention group and the children from other two schools (one boy and one girl) will be allocated into intensified intervention group . Parents of children in clinical trial phase of this study will receive letter in which the study design will explain and they will ask to give their informed consent. Follow-up examinations of caries increment, extent of carious lesion using ICDAS index according to Braga et al (2009) (16) at 3, 6 months for children in both groups. Children will be asked in each follow up about if they wash their mouth after each eating.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. schoolchildren aged 8-10 years old 2. cooperative children 3. children with consent parent
Exclusion criteria 1. children with systemic diseases 2. uncooperative children 3. Disabled children 4. Hereditary developmental defect of teeth . 5. Known allergy /sensitivity to any of dental material that will be used

Intervention groups

Basic intervention (control group) will consist of : 1. Oral health education. 2. Incentive package
Intensified intervention: 1. F-varnish will be applied every 3 months on the all tooth surfaces. 2. 38% silver diamine fluoride.

Main outcome variables

1. Caries progression, 2. Caries increment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220627055297N1**

Registration date: **2022-07-23, 1401/05/01**

Registration timing: **prospective**

Last update: **2022-07-23, 1401/05/01**

Update count: **0**

Registration date

2022-07-23, 1401/05/01

Registrant information

Name

Hanan Alautry

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2242 1813

Email address

hananfadhil@uowasit.edu.iq

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-01, 1401/07/09

Expected recruitment end date

2023-05-15, 1402/02/25

Actual recruitment start date

2022-10-01, 1401/07/09

Actual recruitment end date

2023-05-15, 1402/02/25

Trial completion date

2023-05-15, 1402/02/25

Scientific title

Oral health related quality of life and comparison between preventive regimens among Iraqi preadolescents

Public title

Oral health related quality of life and comparison between preventive regimens among Iraqi preadolescents

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Schoolchildren aged 8-10 years old Cooperative children Children with consent parent

Exclusion criteria:

Children with systemic diseases (blood disease, CVD, diabetes mellitus, asthmatic children) Uncooperative children Disabled children Hereditary developmental defect of teeth such as amelogenesis imperfecta and dentinogenesis imperfecta. Known allergy /sensitivity to any of dental material that will be used

Age

From **8 years** old to **10 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **372**

Actual sample size reached: **372**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Daneshjoo Blvd, Velenjak, Tehran

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2022-05-24, 1401/03/03

Ethics committee reference number

IR.SBMU.DRC.REC.1401.030

Health conditions studied

1

Description of health condition studied

Oral health condition, Dental caries

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes

1

Description

Caries progression

Timepoint

Before intervention, 3, and 6 months after intervention

Method of measurement

International caries Detection and Assessment System (ICDAS) according to Braga et al. (2009) will be used in clinical trial phase . D 0 - Sound D1 - First visual change in enamel (white spot opacity first visible change only after air drying: white, brown). D2 - Distinct visual change in enamel (white spot opacity distinct visible change without air- drying: white, brown). D3 -Localized enamel breakdown due to caries with no visible dentin (localized enamel breakdown surface integrity loss) D4- Non-cavitated surface with underlying dark shadow from dentin (underlying dark shadow +/- surface integrity loss) D5 - Distinct cavity with visible dentin. D6 - Extensive distinct cavity with visible dentin.

Secondary outcomes

1

Description

Caries increment, and Cost – effectiveness of interventions

Timepoint

Before intervention, 3 and 6 months after intervention

Method of measurement

Decay surfaces (DS, dt) according to WHO (2013). Criteria and codes of dental caries: 0 (A). Sound tooth 1 (B). Decayed tooth 2 (C). Filled tooth with decay .Dental caries indices: tooth (DT, dt) and surface levels (DS, ds) carious lesions were registered for all surfaces of each tooth included. The Decayed component (D) included all teeth with codes 1 or 2. Costs of preventive regimen will be examined from the perspective of a service provider:1. Direct medical cost (materials and equipment, capital cost and time spent by service

provider)2. Indirect cost (overhead cost)

Intervention groups

1

Description

Basic intervention group (control group) (standard self-care and oral hygiene practices such as brushing two times a day using fluoridated dentifrices, using dental floss, eating appropriate diet and regular dental visit by oral hygiene instruction, printed material distribution and incentive package providing) and intensified intervention group (professional applications of preventive regimen without drilling procedures include fluoride varnishes and SDF as well as oral health education)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Primary schools

Full name of responsible person

Ahamed Shihab

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GR58+G7V, Al-Hurh St., Kut, Iraq

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hananfadhil@uowasit.edu.iq

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hanan Al_auty

Street address

Department of Community Oral Health, Shahid Beheshti School of Dentistry, Daneshjoo Blvd, Velenjak, Tehran

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Grant name

Grant code / Reference number

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

No

Title of funding source

Hanan Alauty, Shahid Beheshti University of medical Sciences, School of Dentistry

Proportion provided by this source

100

Public or private sector

Private

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

Hanan Alauty

Position

Phd candidate

Latest degree

Master

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Position

Phd candidate

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available