

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparison of anticandidal efficacy of Silver Diamine Fluoride and Chlorhexidine in children with severe early childhood caries

#### Protocol summary

##### Study aim

Evaluating anticandidal effect of Silver Diamine Fluoride versus Chlorhexidine in children with severe early childhood caries

##### Design

randomized clinical parallel group trial, single blind, with control group, phase 4 on 30 patients. for generation of random allocation sequence free website of "www.randomization.com" will be used.

##### Settings and conduct

Tooth decay is a common problem in children. beside streptococcus mutans which is the most common cariogen, candida albicans colonies are detected in cases of early childhood caries and a number of studies showed cariogenic characteristics for these colonies. the study will be conducted in pediatric department of babol dental university. after randomization and confirming positive culture of primary samples, clean and dry tooth surfaces will be treated with silver diamine fluoride or chlorhexidine and patients will receive oral hygiene instructions. 2 and 30 days after treatment patients will be followed up and plaque samples of each step would be sent to the laboratory for colony counting.

##### Participants/Inclusion and exclusion criteria

Healthy children with no systemic condition, younger than 5 years old, and with severe early childhood caries and positive fungal culture of dental plaque would be entered the study. Children who underwent either antibiotic, antifungal or fluoride therapy within the last 1 month, children with orthodontic or prosthodontic appliances or children with special health care needs and the ones with no written informed consent would be excluded from the study.

##### Intervention groups

There are 2 treatment groups: case group in which patients receive a single 38% Silver Diamine Fluoride Solution treatment and control group in which patient receive a single 1% Chlorhexidine gel treatment

##### Main outcome variables

Candida albicans colony count 2 and 30 days after the treatment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201104049255N1**

Registration date: **2021-05-08, 1400/02/18**

Registration timing: **prospective**

Last update: **2021-05-08, 1400/02/18**

Update count: **0**

##### Registration date

2021-05-08, 1400/02/18

##### Registrant information

##### Name

Mina Yazdizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3229 1408

##### Email address

mn.yazdizadeh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-04, 1400/03/14

##### Expected recruitment end date

2021-09-05, 1400/06/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of anticandidal efficacy of Silver Diamine Fluoride and Chlorhexidine in children with severe early childhood caries

**Public title**

Comparison of anticandidal efficacy of Silver Diamine Fluoride and Chlorhexidine in children with severe early childhood caries

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Children younger than 5 years old Children with severe early childhood caries (according to defs scale) Healthy children with no systemic condition Children with positive Candida albicans culture of dental plaque

**Exclusion criteria:**

Children who underwent either antibiotic, antifungal or fluoride therapy (systemic or topical) within the last 1 month prior to the study children with orthodontic or prosthodontic appliances special health care needs children children with no written informed consent granted

**Age**

To 5 years old

**Gender**

Both

**Phase**

4

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

2 dental plaque samples will be collected from each patient during pretreatment and follow up phases

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The selected children were allocated into the 2 treatment groups by block randomization, through the generation of random allocation sequence using free website of "www.randomization.com", by pediatric section secretary. Allocation concealment was achieved with numbered, opaque and sealed envelopes containing the treatment allocation cards, which were prepared before the trial.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Allocation concealment was achieved with numbered, opaque and sealed envelopes containing the treatment allocation cards, which were prepared before the trial. all dental plaque samples will be delivered to the lab with defined name tags (which only main researcher of the

study is aware of) and there is no information about treatment group attached to the sample tubes. this way the researcher who evaluates outcome and data analyzer stay blind. according to apparent different format of study drugs (solution vs gel) and also possibility of staining of decayed teeth after fluoride therapy with SDF, blinding of main researcher or study patients would not be possible.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

**Street address**

Babol Dental Faculty, Felestin Square, Nooshirvani Blvd, Babol, Iran

**City**

Babol

**Province**

Mazandaran

**Postal code**

4717643633

**Approval date**

2021-03-13, 1399/12/23

**Ethics committee reference number**

IR.MUBABOL.REC.1399.502

**Health conditions studied****1****Description of health condition studied**

Severe early childhood caries

**ICD-10 code**

K02.9

**ICD-10 code description**

Dental caries, unspecified

**Primary outcomes****1****Description**

Dental plaque Candida albicans colony count 2 and 30 days after treatment

**Timepoint**

Dental plaque colony count of Candida at beginning of the study (before the intervention) and 2 and 30 days after treatment with Silver Diamine Fluoride or

Chlorhexidine

**Method of measurement**

candida colony count

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Single topical treatment with 38% Silver Diamine Fluoride solution (Fagamin , Tedequim Argentina)

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Single topical treatment with 1% Chlorhexidine gel (Corsodyl , GlaxoSmithKline U.K.)

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Babol Dental Faculty

**Full name of responsible person**

Mina Yazdizadeh

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Niloofar Jenabian

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www.dentpajooeshi@Yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Babol University of Medical Sciences

**Proportion provided by this source**

100

**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**

Babol University of Medical Sciences

**Full name of responsible person**

Mina Yazdizadeh

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Nilgoon Pasdar

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Latest degree**

Medical doctor

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is 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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

antifungal effects of silver diamine fluoride all collected deidentified IPD are would be shared

**When the data will become available and for how long**

The data will become available 6 months after publication

**To whom data/document is available**

people working in businesses can also apply to receive it

**Under which criteria data/document could be used**

people working in businesses can apply to receive the data to update their policies in producing caries preventive materials

**From where data/document is obtainable**

mina yazdizadeh DDS E-mail: mn.yazdizadeh@gmail.com

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

one would have access to the data around 1 month after requesting via email

**Comments**