Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Street address

Babol Dental Faculty, Babol University of Medical Sciences, Felestin Square, Nooshirvani Blvd, Babol, Iran

City

Babol

Province

Mazandaran

Postal code

4717643633

Phone

+98 11 3229 1408

Fax

+98 11 3229 1093

Email

Mn.yazdizadeh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Niloofar Jenabian

Street address

Babol Dental Faculty, Babol University of Medical Sciences, Felestin Square, Nooshirvani Blvd, Babol, Iran

City

Babol

Province

Mazandaran

Postal code

4717643633

Phone

+98 11 3229 1408

Fax

+98 11 3229 1093

Email

www.dentpajooheshi@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

Street address

Babol Dental Faculty, Babol University of Medical Sciences, Felestin Square, Nooshirvani Blvd, Babol, Iran

City

Babol

Province

Mazandaran

Postal code

4717643633

Phone

+98 11 3229 1408

Fax

Email

Mn.yazdizadeh@gmail.com

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

Street address
Babol Dental Faculty, Babol University of Medical Sciences, Felestin Square, Nooshirvani Blvd, Babol, Iran

City
Babol

Province
Mazandaran

Postal code
4717643633

Phone
+98 11 3229 1408

Email
Nilgoonpasdar@yahoo.com

Person responsible for updating data

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

Street address
Babol Dental Faculty, Babol University of Medical Sciences, Felestin Square, Nooshirvani Blvd, Babol, Iran

City
Babol

Province
Mazandaran

Postal code
4717643633

Phone
+98 11 3229 1408

Fax

Email
Mn.yazdizadeh@gmail.com

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 od siver 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