

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

A Comparative Study on the Comparison of Current Infant formula in Iranian Market

Protocol summary

Study aim

A Comparative Study on the Comparison of Current Infant formula in Iranian Market

Design

A clinical trial with 10 dentistry students and 60 samples, blinded, randomized

Settings and conduct

At first, the participants are divided into two groups of four and two using simple random method. In this way, each group randomly uses one of the products per week. Intervention is performed with 10 cc of one of the Infant formulas of Aptamil 3, NAN 3 and Bebelac 3 with one-week interval. In each session, the pH of the dental plaque base is measured by the testator at the site, in the area between the distal surface of the first premolar and the second mesenteric surface of the premolars, in all four quadrants of the mouth. The person tested then holds ten cubic meters of the infant formula in mouth for two minutes and then swallows. The pH of the plaque at designated sites of all four quadrants is measured at five, ten, twenty and sixty minutes after the application of the solution using Metrohm Microelectrode connected to the digital PH Meter. The participants in the study did not know the type of tested milk (between the three studied types).

Participants/Inclusion and exclusion criteria

Entrance: Complete systemic health and not taken antibiotics two weeks before starting the test and not diagnosed with dry mouth
Departure: Active dental caries and tooth filling in the examined area

Intervention groups

Intervention is performed with 10 cc of one of the Infant formulas of Aptamil 3, NAN 3 and Bebelac 3 with one-week interval.

Main outcome variables

In this study, the average of pH of the plaque at the time of the examination, separately the three materials tested in the all quadrants are determined and the rate of dental caries was checked and compared.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171224038033N1**

Registration date: **2018-06-05, 1397/03/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-05, 1397/03/15**

Update count: **0**

Registration date

2018-06-05, 1397/03/15

Registrant information

Name

Sara Bahman

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-05, 1397/03/15

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Study on the Comparison of Current Infant formula in Iranian Market

Public title

A Comparative Study on the Comparison of Current Infant formula in Iranian Market

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Complete systemic health Not taken antibiotics two weeks before starting the test No special diet Not diagnosed with Xerostomia No use of orthodontic or prosthetic appliance

Exclusion criteria:

Smoking Pregnancy Diagnosed Periodontal disease Active dental caries Tooth filling in the examined area

Age

From **20 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **10**

More than 1 sample in each individual

Number of samples in each individual: **60**

The sample of approximately 1 mg of plaque from each quadrant will collect for every measurement

Randomization (investigator's opinion)

Randomized

Randomization description

At the first, the participants are divided into two groups of four and a group of two randomly into a draw method.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants in the study did not know the type of tested milk (between the three studied types).

Placebo

Not used

Assignment

Crossover

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

7th Floor, Bldg No.2, Shahid Beheshti University of

Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Chamran highway, Tehran, Iran.

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Approval date

2017-10-17, 1396/07/25

Ethics committee reference number

IR.SBMU.RIDS.REC.1396.539

Health conditions studied

1

Description of health condition studied

Dental caries

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Dental plaque pH

Timepoint

Before intervention and at intervals of 5-10-20-60 minutes after intervention

Method of measurement

Dental plaque pH - Microelectrode

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention is Aptamil 3 infant formula. At first, the participants are divided into two groups of four and two using simple random method and the interval of one week is considered as washout. In this way, each group randomly uses one of the products per week.

Intervention is performed with 10 cc of one of the Infant formulas of Aptamil 3, NAN 3 and Bebelac 3 with one-week interval. The Aptamil 3 Infant formula is manufactured by Nutrition Company, NAN 3 made by Milupa, and Bebelac 3 is made by Nestle Corporation. The ingredients of the products studied are based on the information on the packaging, including protein, energy, casein, fat, linoleic acid, AA, DHA, carbohydrate, lactose, etc., as described in the table. In each session, the pH of the dental plaque base is measured by the testator at the site, in the area between the distal surface of the first premolar and the second mesenteric surface of the premolars, in all four quadrants of the mouth. The person tested then holds ten cubic meters of the infant formula

in mouth for two minutes and then swallows. The pH of the plaque at designated sites of all four quadrants is measured at five, ten, twenty and sixty minutes after the application of the solution using Metrohm Microelectrode (Ω Metrohm Switzerland LL micro glass electrode) connected to the digital PH Meter (Swiss- Metrohm). It should be noted that the microelectrode is washed prior to the start of each test and at intervals of each reading with a solution 3 KCL model (pH = 7) calibrated with distilled water flow. Meanwhile, for disinfection of the electrode for intervals between the subjects, 2% glutaraldehyde solution is used for 20 minutes. The average pH at the time of the examination, separately the three materials tested in the all quadrants are determined. The results of the study were analyzed by Repeated measure ANOVA with a significance level of $p < 0.05$. In every 100gr of Apyamil 3 infant formula: Energy : 460 Kcal - Protein : 15.4 gr - Whey protein : 5.8 gr - Casein : 9.5 gr - Fat : 20.3 gr - Linoleic acid : 2693 mg - Alpha Linoleic Acid : 496 mg - carbohydrates: 52.6 g - Lactose : 50 g - Fiber : 3.8 g - Sodium : 220 mg - Potassium : 710 mg - Chlorine : 460 mg - Calcium : 640 mg - Phosphorus : 406 mg - Ratio of calcium and phosphorus : 1.6 - Magnesium : 53 mg - Iron : 7 mg - Zinc : 4.3 mg - Copper : 280 μ g - Iodine : 101 μ g - Manganese : 52 μ g - Selenium : 13 μ g - Vitamin A : 447 μ g - Vitamin D : 10.7 μ g - Vitamin B1 : 412 μ g - Vitamin B2 : 1000 μ g - Vitamin B6 : 326 μ g - Vitamin B12 : 1.6 μ g - Biotin : 14 μ g - Folic acid : 87 μ g - Niacin : 3.2 mg - Pantothenic Acid : 3072 μ g - Vitamin C : 66 mg - Vitamin K : 38 μ g - Vitamin E : 8 mg - Cytidine : 7.4 mg - Uridine : 5.3 mg - Adenosine : 4.6 mg - Guanosine : 1.6 mg - Inosine : 3.1 mg - Taurine : 37 mg - Choline : 88 mg - Inositol : 35 mg - L-Carnitine : 9 mg

Category

Prevention

2

Description

The first intervention is Nan 3 infant formula. At first, the participants are divided into two groups of four and two using simple random method and the interval of one week is considered as washout. In this way, each group randomly uses one of the products per week. Intervention is performed with 10 cc of one of the Infant formulas of Aptamil 3, NAN 3 and Bebelac 3 with one-week interval. The Aptamil 3 Infant formula is manufactured by Nutrition Company, NAN 3 made by Milupa, and Bebelac 3 is made by Nestle Corporation. The ingredients of the products studied are based on the information on the packaging, including protein, energy, casein, fat, linoleic acid, AA, DHA, carbohydrate, lactose, etc., as described in the table. In each session, the pH of the dental plaque base is measured by the testator at the site, in the area between the distal surface of the first premolar and the second mesenteric surface of the premolars, in all four quadrants of the mouth. The person tested then holds ten cubic meters of the infant formula in mouth for two minutes and then swallows. The pH of the plaque at designated sites of all four quadrants is measured at five, ten, twenty and sixty minutes after the application of the solution using Metrohm Microelectrode

(Ω Metrohm Switzerland LL micro glass electrode) connected to the digital PH Meter (Swiss- Metrohm). It should be noted that the microelectrode is washed prior to the start of each test and at intervals of each reading with a solution 3 KCL model (pH = 7) calibrated with distilled water flow. Meanwhile, for disinfection of the electrode for intervals between the subjects, 2% glutaraldehyde solution is used for 20 minutes. The average pH at the time of the examination, separately the three materials tested in the all quadrants are determined. The results of the study were analyzed by Repeated measure ANOVA with a significance level of $p < 0.05$. Energy : 497 Kcal - Protein : 14.9 gr - Fat : 23.3 gr - Linoleic acid : 3.20 gr - Alpha Linoleic Acid : 400 mg - carbohydrates: 57 g - Lactose : 50 gr - Sodium : 160 mg - Potassium : 520 mg - Chlorine : 340 mg - Calcium : 500 mg - Phosphorus : 350 mg - Magnesium : 46 mg - Iron : 7.5 mg - Zinc : 6 mg - Copper : 0.3 mg - Iodine : 115 μ g - Manganese : 25 μ g - Selenium : 10.5 μ g - Vitamin A : 390 μ g - Vitamin D : 7.25 μ g - Vitamin B1 : 0.84 μ g - Vitamin B2 : 1.32 mg - Vitamin B6 : 0.4 mg - Vitamin B12 : 1.1 μ g - Biotin : 14.2 μ g - Folic acid : 108 μ g - Niacin : 3.7 mg - Pantothenic Acid : 4.65 mg - Vitamin C : 60 mg - Vitamin K : 40 μ g - Vitamin E : 8 mg - Choline : 70 mg - Inositol : 36 mg

Category

Prevention

3

Description

The first intervention is Bebelac 3 infant formula. At first, the participants are divided into two groups of four and two using simple random method and the interval of one week is considered as washout. In this way, each group randomly uses one of the products per week. Intervention is performed with 10 cc of one of the Infant formulas of Aptamil 3, NAN 3 and Bebelac 3 with one-week interval. The Aptamil 3 Infant formula is manufactured by Nutrition Company, NAN 3 made by Milupa, and Bebelac 3 is made by Nestle Corporation. The ingredients of the products studied are based on the information on the packaging, including protein, energy, casein, fat, linoleic acid, AA, DHA, carbohydrate, lactose, etc., as described in the table. In each session, the pH of the dental plaque base is measured by the testator at the site, in the area between the distal surface of the first premolar and the second mesenteric surface of the premolars, in all four quadrants of the mouth. The person tested then holds ten cubic meters of the infant formula in mouth for two minutes and then swallows. The pH of the plaque at designated sites of all four quadrants is measured at five, ten, twenty and sixty minutes after the application of the solution using Metrohm Microelectrode (Ω Metrohm Switzerland LL micro glass electrode) connected to the digital PH Meter (Swiss- Metrohm). It should be noted that the microelectrode is washed prior to the start of each test and at intervals of each reading with a solution 3 KCL model (pH = 7) calibrated with distilled water flow. Meanwhile, for disinfection of the electrode for intervals between the subjects, 2% glutaraldehyde solution is used for 20 minutes. The average pH at the time of the examination, separately

the three materials tested in the all quadrants are determined. The results of the study were analyzed by Repeated measure ANOVA with a significance level of $p < 0.05$. Energy : 456 Kcal - Protein : 15 gr - Whey protein : 6 gr - Casein : 9 gr - Fat : 19.6 gr - Linoleic acid : 2640 mg - Alpha Linoleic Acid : 489 mg - carbohydrates: 53.3 g - Lactose : 50.6 g - Fiber : 3.7 g - Sodium : 182 mg - Potassium : 730 mg - Chlorine : 536 mg - Calcium : 638 mg - Phosphorus : 410 mg - Ratio of calcium and phosphorus : 1.6 - Magnesium : 49 mg - Iron : 6.7 mg - Zinc : 4.4 mg - Copper : 268 μg - Iodine : 105 μg - Manganese : 45 μg - Selenium : 13 μg - Vitamin A : 436 μg - Vitamin D : 9.5 μg - Vitamin B1 : 416 μg - Vitamin B2 : 822 μg - Vitamin B6 : 330 μg - Vitamin B12 : 1.3 μg - Biotin : 14 μg - Folic acid : 86 μg - Niacin : 3.1 mg - Pantothenic Acid : 2954 μg - Vitamin C : 61 mg - Vitamin K : 33 μg - Vitamin E : 7.6 mg - Cytidine : 7.1 mg - Uridine : 5 mg - Adenosine : 4.4 mg - Guanosine : 1.5 mg - Inosine : 2.9 mg - Taurine : 34 mg - Choline : 86 mg - Inositol : 32 mg - L-Carnitine : 9.2 mg

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti university of medical science

Full name of responsible person

Fatemeh Ahmadian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Tehranchi

Street address

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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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sara Bahman

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Professor

Latest degree

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Other areas of specialty/work

Dentistry

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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

Sara Bahman

Position

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Latest degree

A Level or less

Other areas of specialty/work

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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