Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Aug 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 testand 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
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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 itervention 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 evry 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 µg – Iodine : 101 µg - Manganese : 52 µg - Selenium : 13 µg - Vitamin A : 447 µg - Vitamin D : 10.7 µg - Vitamin B1 : 412 µg - Vitamin B2 : 1000 µg - Vitamin B6 : 326 µg - Vitamin B12 : 1.6 µg - Biotin : 14 µg - Folic acid : 87 µg – Niacin : 3.2 mg – Pantothenic Acid : 3072 µg - Vitamin C : 66 mg - Vitamin K : 38 µg - 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 itervention 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 µg - Manganese : 25 µg - Selenium : 10.5 µg - Vitamin A : 390 µg - Vitamin D : 7.25 µg - Vitamin B1 : 0.84 µg - Vitamin B2 : 1.32 mg - Vitamin B6 : 0.4 mg - Vitamin B12 : 1.1 µg - Biotin : 14.2 µg - Folic acid : 108 µg – Niacin : 3.7 mg – Pantothenic Acid :4.65 mg - Vitamin C : 60 mg - Vitamin K : 40 µg - Vitamin E : 8 mg – Choline : 70 mg – Inositol : 36 mg

Category

Prevention

3

Description

The first itervention 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
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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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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