Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

The effect Probiotic in Local cutaneous complications In children with gastrointestinal ostoma

Protocol summary

Study aim
Determination of the effect of probiotics on topical complications of gastrointestinal children

Design
Randomized clinical trial of two groups (control and intervention), community based and pragmatic with parallel groups, blinded two-way

Settings and conduct
Obtaining a permit from the Ethics Committee of Mashhad University of Medical Sciences, providing a written letter of reference to the research staff and the Department of Surgery in the doctoral hospital, will begin the operational phase of the study. Males from 6 months to 2 years old undergoing colostomy surgery have been identified and contacted The intervention group receives one probiotic capsule dissolved in 20cc of yogurt per day for one week, and the control group also receives one placebo capsule dissolved in 20 cc of yogurt per day for 1 week. Before the onset of intervention, on the fourth day of consumption of probiotics And the end of a week of taking probiotics, one week after the end of the test intervention Stomach Analysis and Ostomy Skin Tool will be done. Patient and statistical analyzer are blind.

Participants/Inclusion and exclusion criteria
Entry requirement: children with colostomy Non-compliance condition: Dissatisfaction with participation in the intervention

Intervention groups
Add probiotics for one week to the diet of research units in the intervention group Add a placebo for a week to the research units in the control group

Main outcome variables
Performing the SE test and determining the score of the Ostomy Skin Tool in the measurements, before the intervention, and the fourth day of probiotic consumption, after the end of the intervention and one week after the end of the intervention, to determine the stool ph and determine the score for the formation of additional tissue, Stomach around the stoma, the extent of the inflamed position, the change of stoma position

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180306038983N1**
Registration date: **2018-05-23, 1397/03/02**
Registration timing: **retrospective**

Last update: **2018-05-23, 1397/03/02**
Update count: **0**

Registration date
2018-05-23, 1397/03/02

Registrant information

Name
Mahbobeh Ghasemirad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4465 7129

Email address
ghasemiradm931@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-04-12, 1395/01/24

Expected recruitment end date
2017-04-13, 1396/01/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect Probiotic in Local cutaneous complications In children with gastrointestinal ostoma

Public title
the effect Probiotic in cutaneous complications of colostomy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
pediatric with colostomy
Exclusion criteria:
Age
From **6 months** old to **2 years** old
Gender
Both

Phase
4
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
-
Blinding (investigator's opinion)
Double blinded
Blinding description
-
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics Committee of Mashhad University of Medical Sciences
Street address
Ebnesina Ave, Doctora Four-way, University Ave, Mashhad Town
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2016-05-25, 1395/03/05
Ethics committee reference number
IR.MUMS.REC.1395.158

Health conditions studied

1

Description of health condition studied
Colostomy
ICD-10 code
K55-K64
ICD-10 code description
Other Diseases Of Intestines

Primary outcomes

1

Description
Checker tool score the skin around the colostomy
Timepoint
. Before the intervention, the fourth day of intervention, after the end of the care period and one week after the probiotic has stopped, the Ostomy Skin Tool will be checked.
Method of measurement
a tool for checking skin around colostomy(SST)

2

Description
stool acidity
Timepoint
Before the intervention, the fourth day of intervention, after the end of the care period and one week after the interruption of the probiotic, a fecal analysis test will be performed.
Method of measurement
Stool analysis test

Secondary outcomes

1

Description
skin color around colostomy
Timepoint
Before the intervention, the fourth day of intervention, after the completion of the care period and one week after the interruption of the probiotic
Method of measurement
See researcher

2

Description
Stool color
Timepoint
Before the intervention, the fourth day of intervention, after the completion of the care period and one week

after the interruption of the probiotic

Method of measurement

See researcher

3

Description

Consistency of stool

Timepoint

Before the intervention, the fourth day of intervention, after the completion of the care period and one week after the interruption of the probiotic

Method of measurement

See researcher

Intervention groups

1

Description

"Intervention group":After obtaining permission from the Ethics Committee of Mashhad University of Medical Sciences and receiving a written reference from the Mashhad Nursing and Midwifery Faculty, it was submitted to the MSI in the research environment and coordination with the department responsible for the operation of the doctor's hospital and the coordination with the relevant doctors. will be. After co-ordinating with the research environment, referring to the Department of Surgery in the doctor's hospital, the infants from 6 months to 2 years of age who have been undergoing surgical procedures for any of the underlying problems that were under colostomy insertion surgery, or through the information contained in the archives file. They have already been identified and contacted at home clinostomy. In both cases, after their introduction and access to their specifications, they will be given a brief explanation of the goals and manner of doing the research. To The control of the mediating variable of the age range is limited to the lowest difference in diet Be in research units. At the same time, given that the sst tool can accurately display changes in the patient's skin condition over time. In practice, by performing precise follow-up studies in both groups, virtually every patient is self-controlled. Because the forecast sees changes over time. At the first referral of a child, the first choice of the research unit, which includes exclusion criteria and inclusion criteria, will be selected by the researcher through an interview with the patient's mother and the measurement of the child's height and weight, and the eligible patient will be selected. Subsequently, the children eligible for the study Descriptions of the research goals will be presented by the researcher face to face for 10 to 15 minutes. If they wish to participate in the study, they will be informed by the researcher in a written informed consent form, and the individual profile will be completed in an interview and using the patient's case. In order to improve the quality of nursing care from the ulcer in two groups Traveller and intervention Nursing care program from an osteomy is trained in each of the two groups before the intervention begins, and the booksleet is provided to caregivers of the child. The care includes, how to attach and remove the ostomy bag, washing and cleaning the skin around the stoma, teaching a variety of complications Stoma, bathing, swimming, dressing up, sleeping, activities, traveling, walking. The investigator will provide his telephone number to answer questions. Immediately after training, the intervention begins, and is done daily or I contacted the research unit every 3 days to ensure that the care plan is followed To be For this purpose, a checklist is designed that receiving a score of over 75% of the checklist means strict adherence to the program. People who do not receive 75% of the total score are re-educated. This process will be performed in 3 rounds, with up to 3 training sessions, 75% of the score will not be excluded from the research. The evaluation of the full checklist is only done by the researcher. In the case of home-based research units, assessments and reviews can be made by taking pictures by parents and sending them through telegrams or face-to-face visits. To assist in finding research units, a researcher who is responsible for the operating room of Dr. Sheikh Hospital and a graduate student of nursing specialist neonates is introduced due to his constant contact with these patients as a researcher's assistance. Subsequently, the intervention group for one On a weekly basis, one probiotic capsule dissolved in 20cc of yogurt is given. Before the onset of the intervention, on the fourth day of probiotic consumption and the end of a week, a probiotic, a stool analysis, and a Ostomy Skin Tool will be done. The instrument will examine the condition of the skin surrounding the stoma in terms of the extent of the inflammatory position, the excess tissue, and the color change. One week after the intervention: again, all research units will be tested on the stool analysis and the Ostomy Skin Tool. Considering that the parents of the patient And the statistical analyzer did not know how to group the research units into two groups, so a double-blind study would be.

Category

Prevention

2

Description

"Control group": After obtaining permission from the Ethics Committee of Mashhad University of Medical Sciences and receiving a written reference from the Mashhad Nursing and Midwifery Faculty, it was submitted to the Medical Research Center and coordinated with the Department of Surgery of Dr Shaikh Hospital and coordination with the relevant physicians. will be. After co-ordinating with the research environment, referring to the Department of Surgery in the doctor's hospital, the infants from 6 months to 2 years of age who have been undergoing surgical procedures for any of the underlying problems that were under colostomy insertion surgery, or through the information contained in the archives file. They have already been identified and contacted at home clinostomy. In both cases, after their introduction and access to their specifications, they will be given a brief explanation of the goals and manner of doing the research. To The control of the mediating variable of the

age range is limited to the lowest difference in diet Be in research units. At the same time, given that the sst tool can accurately display changes in the patient's skin condition over time. In practice, by performing precise follow-up studies in both groups, virtually every patient is self-controlled. Because the forecast sees changes over time. At the first referral of a child, the first choice of the research unit, which includes exclusion criteria and inclusion criteria, will be selected by the researcher through an interview with the patient's mother and the measurement of the child's height and weight, and the eligible patient will be selected. Subsequently, the children eligible for the study Descriptions of the research goals will be presented by the researcher face to face for 10 to 15 minutes. If they wish to participate in the study, they will be informed by the researcher in a written informed consent form, and the individual profile will be completed in an interview and using the patient's case. In order to improve the quality of nursing care from the ulcer in two groups Traveller and intervention Nursing care program from an osteomy is trained in each of the two groups before the intervention begins, and the booksleet is provided to caregivers of the child. The care includes, how to attach and remove the ostomy bag, washing and cleaning the skin around the stoma, teaching a variety of complications Stoma, bathing, swimming, dressing up, sleeping, activities, traveling, walking. The investigator will provide his telephone number to answer questions. Immediately after training, the intervention begins, and is done daily or I contacted the research unit every 3 days to ensure that the care plan is followed To be For this purpose, a checklist is designed that receiving a score of over 75% of the checklist means strict adherence to the program. People who do not receive 75% of the total score are re-educated. This process will be performed in 3 rounds, with up to 3 training sessions, 75% of the score will not be excluded from the research. The evaluation of the full checklist is only done by the researcher. In the case of home-based research units, assessments and reviews can be made by taking pictures by parents and sending them through telegrams or face-to-face visits. To assist in finding research units, a researcher who is in charge of the operating room of Dr. Sheikh Hospital and a graduate student of nursing specialist neonates is introduced due to his constant contact with these patients as a researcher's assistance. Continuing the control group for one Each week, one capsule of placebo is dissolved in 20 cc of yogurt (yasir). The placenta is starchy and looks like a probiotic capsule. Before the onset of the intervention, on the 4th day of the placebo and the end of one week, the placebo was taken, the analytical test Stool and Ostomy Skin Tool. The instrument will examine the status of the skin around the stoma in terms of the extent of the inflamed position, the extra tissue, and the color change. One week after the intervention, all research units will be tested on the stool analysis and the Ostomy Skin Tool. Given that the parents are sick and The statistical analyzer did not know how to group the research units into two groups, so a double-blind study would be.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Sheikh Hospital

Full name of responsible person
Mahboobeh Ghasemirad

Street address
Shahid Gharani St 6, Taheri St, Tohid Square, Dr Sheikh Hospital

City
Mashhad

Province
Razavi Khorasan

Postal code
-

Phone
+98 51 3726 9021

Fax

Email
Ghasemiradm931@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Saeed Islami

Street address
Ebnesina Ave, Doctora Four-way, University Ave, Mashhad Town

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

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Ghasemiradm931@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mahboobeh Ghasemirad

Position

Student Master

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Unit B3, Bahar Building, Razi Street 9, Razi Blvd

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Province

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Ghasemiradm931@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahboobeh Ghasemirad

Position

Student Master

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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9618611111

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahboobeh Ghasemirad

Position

Student Master

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Email

Ghasemiradm931@mums.ac.ir

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