Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

The effect of oral consumption of lettuce syrup on breast milk volume and weight gain of preterm infants

Protocol summary

Study aim
Determining the effect of oral consumption of Lactuca sativa syrup on breast milk volume and weight gain of preterm infant

Design
Three-group clinical trial (test, placebo and control).Participants will be randomly assigned to six blocks in three groups.

Settings and conduct
This study will be performed as a three-group randomized clinical trial in parallel on 144 lactating women and premature infants under 32 weeks of age in the neonatal intensive care unit of Shahid Akbarabadi Hospital. The mothers of the experimental group will receive a 240 ml Lactuca sativa syrup and the mothers of the placebo group will receive a placebo syrup. it is recommended that they consume one tablespoon 3 times a day, for a week.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Mothers interest to exclusive breastfeeding, mothers interest to pumping breast, have minimum 18 years old, have normal body mass index, present of mother in hospital, preterm infant with gestational age less than 32 weeks, Infant hospitalization in NICU fed with NG tube; Criteria for non-entry: Use of cigarette, alcohol and drugs, use of any galactogogue and complementary drug, affliction of mother to infectious transferable diseases from lactating such as HIV and active pulmonary Tuberculosis, history of infertility, diabetic mother, mother use of anticoagulation, mothers with cancer related to estrogen, Taking psychiatric drugs, performance of breast surgery, Breast problems such as abscesses, inverted nipples, mastitis or cancer,Premature birth defects such as cleft palate and cleft lip, Supplementation by the infant, Twin or multiple infants.

Intervention groups
The experimental group will receive one Lactuca sativa syrup, the placebo group one placebo syrup and the control group will not receive any herbal or chemical milking compound.

Main outcome variables
Breast milk volume and weight gain of preterm infant

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180427039436N12**
Registration date: **2021-12-14, 1400/09/23**
Registration timing: **prospective**

Last update: **2021-12-14, 1400/09/23**
Update count: **0**

Registration date
2021-12-14, 1400/09/23

Registrant information

Name
Leila Amiri Farahani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 4365 1139

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l.amirifarahani@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-05-22, 1401/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of oral consumption of lettuce syrup on breast milk volume and weight gain of preterm infants

Public title
The effect of oral consumption of lettuce syrup on breast milk volume and weight gain of preterm infants
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
have minimum 18 years old Mother's ability to read and write Have normal maternal body mass index (18/5 - 24/9 kg / m2) mothers interest to exclusive breastfeeding mothers interest to pumping breasts witt electronic pumping from third day of postpartum presence of the mother in the hospital during the study Preterm infant with gestational age less than 32 weeks Infant hospitalization in NICU fed with NG tube
Exclusion criteria:
Use of cigarette, alcohole and drugs Use of any galactagogue and complementary drug History of infertility Affiliction of mother to infectious transferable diseases from lactating such as HIV and active pulmonary tuberculosis Diabetic mother Mothers with cancer related to estrogen Mother use of anticoagulants Mother use of psychiatric drugs Breast problems such as abscesses, inverted nipples, mastitis or cancer Breast surgery Existence of congenital anomalies such as cleft palate and cleft lip Supplementation by the infant Twin or multiple infants
Age
From **8 months** old to **8 months** old
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **144**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples that were continuously included in the study will be randomly assigned by six blocks in a one-to-one ratio in the three experimental, placebo, and control groups. For random assignment of people in three groups, the random blocking method from https://www.sealedenvelope.com/ is used. A person outside the research team prepares a random list of people and the code of consumed syrups through the site https://www.sealedenvelope.com/ (information needed to achieve random allocation and concealment of research samples including the number of treatment groups (treatment groups), the number of blocks and the size of each (block sizes), the number of people participating in the study, determine the need for a coding code for each participant (generate unique randomization code). The site issues a two-digit code and a number for each sample, which specifies exactly which block and for which group the sample is from. The package and the sample we want are known by the code and number inserted).
Blinding (investigator's opinion)
Single blinded
Blinding description
There is no possibility of blinding in the present study due to having a control group and only to increase the accuracy of the study, the researcher will not know the content of syrup given to individuals in each group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
In front of Khatamol anbiaa Hospital., Rashid Yasemi Ave., Valiasr Ave.,Tehran Town
City
Tehran
Province
Tehran
Postal code
1981111198
Approval date
2021-10-27, 1400/08/05
Ethics committee reference number
IR.IUMS.REC.1400.671

Health conditions studied

1

Description of health condition studied
The effet of oral consumption of Lactuca sativa syrup on breast milk volume and weight gain of preterm infant
ICD-10 code
P07.3
ICD-10 code description
Preterm [premature] newborn [other]

Primary outcomes

1

Description

Determining breast milk volume

Timepoint

Measurement of breast milk volume on days 1, 2, 3, 4, 5, 6 and 7 of the study

Method of measurement

Measurement of milk volume in mothers through sweetheart medela AND

2

Description

Determining weight gain of preterm infant

Timepoint

Measurement of preterm infant weight on day one (before intervention), day three and day seven

Method of measurement

Measurement of weight of preterm infant through a Seca scale production of Germane

Secondary outcomes

1

Description

Pharmacological complication

Timepoint

During one week of study

Method of measurement

Mothers will notify the researcher whose telephone number is provided to the mothers if they notice any allergies or complications during the study.The researcher registers the complication in the drug side effects registration form and takes the appropriate action.

Intervention groups

1

Description

Intervention group: Mothers in the experimental group will receive a 240 ml Lactuca sativa syrup. In this research, 240 ml of Lactuca sativa syrup (Noma) made by Sanabel Daroo Company, with Iran Food and Drug Code with registration number "0545 -95-S" will be used. Lettuce syrup is based on total phenol, containing at least 10 mg per 10 gr of standard syrup. They are advised to consume one tablespoon 3 times a day, half an hour after breakfast, lunch and dinner for a week. The researcher teaches mothers how to use a breast pump by placing a flange, which is the breast protector, on their nipple.Turn on the machine and allow the milk to be sucked and poured into a container attached to the milking parlor. It takes between 10 and 15 minutes to pump both breasts with a good electric milking machine. good milking machine simulates baby sucking and does not cause pain. At first, mothers may feel a lot of traction from their automatic breastfeeding, so it is best to start with the lowest degree of suction And increase the degree as needed during the habit. It will also teach them to be calm and comfortable, first wash their hands before starting to milk and do not forget to carefully clean the parts of the machine after each use of the milk. The hospital milking machine is provided to mothers. Breastfeeding using Medla Electronic milking machine is performed by the mother on waking at least 6 times in 12 hours during a 7 day study period for 15 minutes on both breasts and The milk is poured into a container attached to the milking machine. All mothers are instructed to count the number and time spent breast pumping daily (in minutes), the volume of breast milk at each pumping, the time spent skin-to-skin contact (kangaroo care) with their premature baby, Manually, enter the daily information registration form within 7 days. The trained researcher or assistant researcher will also record the type and amount of serum consumed in the daily information form in the case of neonatal serum therapy. Mothers give their milk to their premature infants (under 32 weeks) according to the doctor's instructions, and If there is a lot of milk and more than the infant needs, according to the mother's consent, in completely standard conditions, they will store it in the milk bank of Shahid Akbarabadi Hospital or Is thrown away.

Category

Other

2

Description

Intervention group: Mothers in the placebo group will receive a placebo syrup based on the syrup base formula (meaning the syrup base, sugar, and color combinations to simulate Lactuca sativa syrup).In this research, 240 ml placebo syrup made by Sanabel Daroo Company, made in Iran, is used.They are advised to consume one tablespoon 3 times a day, half an hour after breakfast, lunch and dinner for a week.The researcher teaches mothers how to use a breast pump by placing a flange, which is the breast protector, on their nipple.Turn on the machine and allow the milk to be sucked and poured into a container attached to the milking parlor. It takes between 10 and 15 minutes to pump both breasts with a good electric milking machine. good milking machine simulates baby sucking and does not cause pain. At first, mothers may feel a lot of traction from their automatic breastfeeding, so it is best to start with the lowest degree of suction And increase the degree as needed during the habit. It will also teach them to be calm and comfortable, first wash their hands before starting to milk and do not forget to carefully clean the parts of the machine after each use of the milk. The hospital milking machine is provided to mothers. Breastfeeding using Medla Electronic milking machine is performed by the mother on waking at least 6 times in 12 hours during a 7 day study period for 15 minutes on both breasts and The milk is poured into a container attached to the milking machine. All mothers are instructed to count the number and time spent breast pumping daily (in minutes), the volume of breast milk at each pumping, the time spent skin-to-skin contact (kangaroo care) with their premature baby, Manually, enter the daily information registration

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Category

Other

3

Description

Control group: Mothers in the control group will not receive any herbal or chemical formula. The researcher teaches mothers how to use a breast pump by placing a flange, which is the breast protector, on their nipple.Turn on the machine and allow the milk to be sucked and poured into a container attached to the milking parlor. It takes between 10 and 15 minutes to pump both breasts with a good electric milking machine. good milking machine simulates baby sucking and does not cause pain. At first, mothers may feel a lot of traction from their automatic breastfeeding, so it is best to start with the lowest degree of suction And increase the degree as needed during the habit. It will also teach them to be calm and comfortable, first wash their hands before starting to milk and do not forget to carefully clean the parts of the machine after each use of the milk. The hospital milking machine is provided to mothers. Breastfeeding using Medla Electronic milking machine is performed by the mother on waking at least 6 times in 12 hours during a 7 day study period for 15 minutes on both breasts and The milk is poured into a container attached to the milking machine. All mothers are instructed to count the number and time spent breast pumping daily (in minutes), the volume of breast milk at each pumping, the time spent skin-to-skin contact (kangaroo care) with their premature baby, Manually, enter the daily information registration form within 7 days. The trained researcher or assistant researcher will also record the type and amount of serum consumed in the daily information form in the case of neonatal serum therapy. Mothers give their milk to their premature infants (under 32 weeks) according to the doctor's instructions, and If there is a lot of milk and more than the infant needs, according to the mother's consent, in completely standard conditions, they will store it in the milk bank of Shahid Akbarabadi Hospital or Is thrown away.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbarabadi Hospital

Full name of responsible person

niloufar izaddoost

Street address

In front of Khatamol anbiaa Hospital., Rashid Yasemi Ave., Valiasr Ave.,Tehran Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein Kiwani

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person
Leila Amirifarahani
Position
Associate professor
Latest degree
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Other areas of specialty/work
Reproductive Health
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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