

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 galactagogue 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)

Phone

+98 21 4365 1139

Email address

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 with 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, alcohol and drugs Use of any galactagogue and complementary drug History of infertility Affiliation 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

AgeFrom **8 months** old to **8 months** old**Gender**

Both

Phase

3

Groups that have been masked

- Data analyser

Sample sizeTarget 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 effect 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

City

Tehran

Province

Tehran

Postal code

1981111198

Phone

+98 21 4365 1139

Email

izaddoost.nlf@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein Kiwani

Street address

Shahid hemat highway, Direction2., Tehran Town

City

Tehran

Province

Tehran

Postal code

1981111198

Phone

+98 21 6543 3911

Email

L.amirifarahani@gmail.com

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

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

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

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 4365 1139

Email

L.amirifarahani@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Iran University of Medical Sciences

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

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

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 4365 1139

Email

L.amirifarahani@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Iran University of Medical Sciences

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

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+98 21 4365 1139

Email

L.amirifarahani@gmail.com

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