Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of breast milk smell and vanilla extract on the duration of the transition from gavage to oral feeding, weighing, and length of stay of premature infants in special care units of hospitals affiliated with Shiraz University of Medical Sciences in 2023-2024

Protocol summary

Study aim
Comparison of the effect of the smell of breast milk and vanilla extract on the duration of the transition from gavage to oral feeding, weighing, and length of stay of premature infants

Design
Clinical trial with control group, with parallel groups, randomized, 61 infants

Settings and conduct
At the beginning of the study, completing the checklist of demographic characteristics, measuring the baby's weight using a scale. In the first intervention group, olfactory stimulation with a pad soaked in 1 cc of a concentration of 6 mg in 100 cc of vanilla extract. In the second intervention group, olfactory stimulation with a pad soaked in 1 cc of breast milk. In the control group, olfactory stimulation with a pad soaked in 1 cc of sweet almond oil. After completing the interventions, re-measure the baby's weight using a scale. The place of interventions is the neonatal intensive care unit of hospitals affiliated to Shiraz University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Inclusion: breastfeeding. Exclusion: Previous patient participation in studies similar to the current study.

Intervention groups
The Intervention group with mother's milk scent during gavage The intervention group with the scent of vanilla extract during gavage Control group, without any intervention of gavage feeding.

Main outcome variables
The duration of the transition from gavage to oral feeding, weighing, and length of stay

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160228026817N4**
Registration date: **2023-05-10, 1402/02/20**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-10, 1402/02/20**
Update count: **0**

Registration date
2023-05-10, 1402/02/20

Registrant information

Name
Neda Jamalimoghadam

Name of organization / entity
Shiraz university of medical science

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-04, 1402/02/14

Expected recruitment end date
2023-08-05, 1402/05/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of breast milk smell and vanilla extract on the duration of the transition from gavage to oral feeding, weighing, and length of stay of premature infants in special care units of hospitals affiliated with Shiraz University of Medical Sciences in 2023-2024

Public title
Comparison of the effect of the smell of breast milk and vanilla extract on the duration of the transition from gavage to oral feeding, weighing, and length of stay of premature infants

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Gestational age 27-33 weeks (who have weakness and inability to suck) Birth weight of at least 1 Kg Apgar score greater than 6 in the first and fifth minutes Not having any health-threatening congenital abnormalities No underlying or acquired diseases except prematurity Breast feeding

Exclusion criteria:
Previous patient participation in studies similar to the current study

Age
From **1 day** old to **30 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **61**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, the permuted block method will be used and people in three groups will be assigned to 10 blocks of 6. Allocation will be done by Random allocation software. In order to assign people to three groups, the intervention group with the scent of vanilla with the English letter A, the intervention group with the scent of mother's milk with the English letters B, and the control group with the English letters C are considered, and the different permutations of the ABC chain are written and given a code. The codes are CBA, CAB, BAC, ACB, ABC, and each time the groups are assigned, a number between 1 and 6 is randomly selected.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Zand Street, in front of Palestine Street, Shiraz University of Medical Sciences

City
Shiraz

Province
Fars

Postal code
7134814336

Approval date
2023-04-29, 1402/02/09

Ethics committee reference number
IR.SUMS.NUMIMG.REC.1401.112

Health conditions studied

1

Description of health condition studied
The duration of transition from gavage to oral feeding, weighing and length of stay of premature babies

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The duration of the transition from gavage to oral feeding

Timepoint
The distance from the start of gavage feeding to oral feeding

Method of measurement
According to the patient's file

2

Description
Weighing

Timepoint
Birth weight, weight at entry into the study, and weight at the time of feeding transfer

Method of measurement
Scale

3

Description

Duration of Stay of premature babies

Timepoint

According to the patient's file

Method of measurement

Registration in the patient file

Secondary outcomes

1

Description

Improving the quality of life

Timepoint

From admission to discharge

Method of measurement

The number of hospitalization days of infants in the intervention group is compared with the control group and recorded in the designed table.

2

Description

Decreasing parental anxiety

Timepoint

Birth weight, weight at the time of intervention, and weight at the time of discharge is measured

Method of measurement

Standard digital scale available in the department

Intervention groups

1

Description

First intervention group: Vanilla. In the present study, simultaneously with the start of gavage, olfactory stimulation was performed in the intervention group with a pad soaked in 1 cc of a concentration of 6 mg in 100 ccs of vanilla extract at 9 am, 12 noon, 3 pm, and 6 pm. Gavage is completed and olfactory stimulation is removed, which continues until the mother's breastfeeding begins.

Category

Other

2

Description

The second intervention group: is breast milk. In the present study, at the same time as the gavage begins, at 9:00 AM, 12:00 PM, 3:00 PM, and 6:00 PM, olfactory stimulation is performed and in the intervention group with a pad soaked in 1 cc of breast milk, and after the end of the gavage And the olfactory stimulus is removed, which continues until the start of feeding from the mother's breast

Category

Other

3

Description

Control group: In the present study, at the same time as the gavage begins, olfactory stimulation is performed in the intervention group with a pad soaked in 1 cc of sweet almond oil at 9 am, 12 noon, 3 pm, and 6 pm, and after the end of the gavage and The olfactory stimulation is removed, which continues until the mother's breastfeeding begins.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals affiliated with Shiraz University of Medical Sciences

Full name of responsible person

Neda Jamalimoghadam

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Namazee square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hashem Hashempur

Street address

Deputy of research and technology, 7th floor, Central Building of Shiraz University of Medical Sciences, Zand St., Shiraz, Fars, Islamic Republic of Iran

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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

Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Neda Jamalimoghadam

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

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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