Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Investigating the effect of ostrich oil on the healing rate of pressure ulcers in premature babies: A randomized controlled clinical trial

Protocol summary

Study aim
Investigating effect of ostrich oil on the healing of pressure ulcers of premature babies.

Design
A clinical trial with intervention and control groups using four and six random block method, double-blinded, on 60 premature babies hospitalized in the NICUs

Settings and conduct
Premature babies hospitalized in one of the neonatal intensive care units (NICU1 or 2) who have pressure ulcers will be included in the study, and the pressure ulcer score will be determined based on the Pressure Ulcer Scale for Healing tool (PUSH). Babies will be assigned into two groups of intervention (routine care + ostrich oil) and control (routine care) using four and six random block method. To conceal the allocation, opaque envelopes will be used and a person not involved in the study will select the envelopes. Based on obtained ulcer score, a written order will be given by the neonatologist to start the treatment. Then ointments and ostrich oil will be applied on babies' pressure ulcers at the prescribed times. The rate of ulcer healing up to 10 days will be checked every 24 hours by the researcher's assistant and using the PUSH tool and the score will be obtained. The researcher's assistance is blinded to the assignment of samples to the study groups due to the lack of direct involvement in the medication of the newborns.

Participants/Inclusion and exclusion criteria
Inclusion criteria: gestational age of 28-32 weeks, hospitalized in NICU, having pressure ulcers require treatment. Exclusion criteria: having congenital /autoimmune skin problems, having skin sensitivities that prohibit ointment application.

Intervention groups
Intervention group: applying ostrich oil in addition to routine care on pressure ulcers of premature babies. Control group: Rubbing routine ointments on the pressure ulcers of premature babies

Main outcome variables
Required time to heal pressure ulcers; Complications of pressure ulcers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220723055528N1**
Registration date: **2024-03-03, 1402/12/13**
Registration timing: **registered_while_recruiting**

Last update: **2024-03-03, 1402/12/13**
Update count: **0**

Registration date
2024-03-03, 1402/12/13

Registrant information

Name
Roya Saboohi khamneh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3551 8383

Email address
saboohi_r@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-21, 1402/11/01

Expected recruitment end date
2024-07-22, 1403/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of ostrich oil on the healing rate of pressure ulcers in premature babies: A randomized controlled clinical trial

Public title
Investigating the effect of ostrich oil on the healing rate of pressure ulcers in premature babies

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Gestational age 28 to 32 weeks Hospitalization in one of the NICU departments 1, 2 of Al-Zahra Hospital The presence of a pressure ulcer that needs treatment (score at least 3 based on the PUSH tool) The written order of the attending physician to carry out the medication orders

Exclusion criteria:
1. Presence of congenital/autoimmune skin problems such as lupus erythematosus or neonatal ichthyosis 2. Existence of skin sensitivities that cause skin irritation or ointment application, which is medically prohibited. 3. Babies admitted from other centers with previous skin irritations

Age
From **1 day** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the selection of babies will be conducted using convenience sampling method and based on inclusion criteria in the first stage. In the next step, included infants will be assigned to two groups of intervention (routine care + ostrich oil) and control (routine care) using the random block method of four and six. In this study, random block design will be used to ensure the balance of the number of participants who enter the intervention and control groups at consecutive time intervals. In this way, for example, intervention (ostrich oil) is randomly assigned to the first block and routine care to the second block, and again intervention (ostrich oil) to the third block and so on. To conceal the assignment of samples to the groups, the code of the groups is written on a sheet of paper and placed inside the opaque envelopes, numbered consecutively, and the assignment of the group code to the samples will be done by a person not involved in the study (department secretary). in such a way that after selecting the eligible sample, the department secretary randomly selects an envelope and according to the code written in it, the baby will be placed in one of the intervention or control groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the nature of the intervention and the difference in the consistency, color and appearance of the routine treatment (ointments) and the desired intervention (ostrich oil) and also due to the recording of the treatments in the cardex of the infants, it was not possible to blind the nurses and the researcher, and the blinding of the researcher's assistance (who will determine the healing scores) and the statistical consultant of the study (who will analyze the data), will be conducted in the stage of scoring the wound and analyzing the data.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
South Shariati St, Faculty of Nursing and Midwifery, Tabriz, Iran.

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Tabriz

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East Azarbaijan

Postal code
5138947977

Approval date
2023-02-07, 1401/11/18

Ethics committee reference number
IR.BZMED.REC.1401.989

Health conditions studied

1

Description of health condition studied
Premature babies with a gestational age of 28 to 32 weeks hospitalized in the neonatal intensive care unit with pressure ulcers caused by medical procedures.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The time required for the healing of pressure ulcers in premature babies caused by medical procedures
Timepoint
Examining the rate of wound healing in two groups up to 7 days every 24 hours using the PUSH tool
Method of measurement
Using Pressure Ulcer Scale for Healing (PUSH)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After determining the pressure ulcer score based on PUSH tool and recording it in the data collection form and completing newborns' demographic characteristics questionnaire based on the medical record, the score obtained from the PUSH tool will be approved by the neonatologist. Then, the written order to start the treatment (routine ointments + ostrich oil) will be given by the neonatologist and recorded in the newborn cardex by the relevant nurse. Ointments and ostrich oil will be applied on the pressure ulcer of the babies at the prescribed times (one in between in equal intervals of 4 or 6 hours). In this study, ostrich oil which prepared in the laboratory of Bani Teb Aria with license number of "0395-94-S" and health license of 1633 and exploitation license of 123/32436 will be used. This oil also has the Sib Salamat logo and is available in 90cc containers in reputable pharmacies across the country. This product is extracted from ostrich visceral environmental fat in a completely pure form and without additives and essential oils. Ostrich oil will be applied by trained nurses on the pressure ulcers of the babies in the amount of 0.5 to 1cc (depending on the size of the ulcer) at the intervals determined by the neonatologist, so that a layer of oil covers the entire surface of the ulcer. Before applying ointments or ostrich oil on the surface of the ulcer, to remove the previously used oil, the desired area will be washed with sterile cotton dipped in lukewarm sterile distilled water and dried. During the treatment period (10 days), the rate of ulcer healing will be checked and recorded every 24 hours using the PUSH tool by the researcher assistant who is an experienced nurse working in the morning shifts and is blinded to the assignment of the samples to the groups.
Category
Treatment - Other

2

Description
Control group: After determining the pressure ulcer score based on PUSH tool and recording it in the data collection form and completing newborns' demographic characteristics questionnaire based on the medical record, the score obtained from the PUSH tool will be approved by the neonatologist. Then, the written order to start the treatment (Unit routine ointments) which is usually given every 8 hours or 12 hours will be given by the neonatologist and recorded in the newborn cardex by the relevant nurse. To use the ordered ointments, according to the size of the wound, the sterile applicator will be smeared with 0.5 to1cc of the ointment and applied as a one layer on the surface of the ulcer at the prescribed times (according to Cardex). Before applying ointments on the surface of the ulcer, to remove the previously used oil, the desired area will be washed with sterile cotton dipped in lukewarm sterile distilled water and dried. During the treatment period (10 days), the rate of ulcer healing will be checked and recorded every 24 hours using the PUSH tool by the researcher assistant who is an experienced nurse working in the morning shifts and is blinded to the assignment of the samples to the groups.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Roya Saboohi Khamneh
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Roya Saboohi Khamneh
Position
Master's student in neonatal intensive care
Latest degree
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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