Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Equisetum arvense (Horse tail) on perineal trauma in primiparous women with striae gravidarum

Protocol summary

Study aim
Determine the effect of Equisetum arvense (Horse tail) on perineal trauma in primiparous women with striae gravidarum

Design
A Randomized clinical trial with a control group, parallel groups, triple blind

Settings and conduct
The present clinical trial will be performed on 60 pregnant women referred to obstetric clinic of Mashhad Omolbanin hospital. Sampling will be performed in convenience method and individuals who meet the inclusion criteria will be entered the study, then the research units will be randomly allocated into intervention and control groups based on the sequence created by a simple randomization online. Coding of medicinal and placebo creams is performed by the pharmacy consultant professor and by the end of the study, research units, the researcher, the statistical analyzer and delivery agent will not know the codes of Equisetum arvense and placebo cream.

Participants/Inclusion and exclusion criteria
Inclusion criteria: primiparous women, 18 to 35 years, gestational age 37 to 38 weeks, Total striae score higher than 9 (Moderate to Severe Striae), Body mass index 18.5 to 30; Exclusion criteria: medical and obstetric problems, vaginal infection, previous vaginal or perineal surgery, vegetarian diet, perineal massage

Intervention groups
individuals in the intervention group will use Equisetum arvense cream (3%) from the 37-38 week of gestation until delivery, once a night before sleeping, and in the placebo group will use moisturizing cream (both creams are made in Pharmacological research center of medicinal plants in Mashhad university of medical sciences) in the perineum and beginning part of vagina. Also at delivery time episiotomy will be performed according to national guidelines and the discretion of delivery agent in both groups if indicated.

Main outcome variables
Degree, length and depth of perineal laceration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200224046605N1**
Registration date: **2020-04-10, 1399/01/22**
Registration timing: **prospective**

Last update: **2020-04-10, 1399/01/22**
Update count: **0**

Registration date
2020-04-10, 1399/01/22

Registrant information

Name
Fatemeh Khademolkhamseh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3228 0125

Email address
khademkf971@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-20, 1399/02/31

Expected recruitment end date
2020-10-21, 1399/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Equisetum arvense (Horse tail) on perineal trauma in primiparous women with striae gravidarum

Public title
The effect of Equisetum arvense (Horse tail) on perineal trauma

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
primiparous women 18 to 35 years gestational age 37 to 38 weeks informed consent to participate in the study Iranian nationality living in Mashhad literacy for reading and writing single pregnancy cephalic presentation Total striae score higher than 9 (Moderate to Severe Striae) Body mass index 18.5 to 30 having Desire To give birth at Omolbanin Hospital

Exclusion criteria:
medical and obstetric problems vaginal infection previous vaginal or perineal surgery drug or alcohol abuse vegetarian diet perineal massage having a history of allergy to herbal medicines

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling is performed at the obstetric clinic of Omolbanin hospital in Convenience Sampling method based on inclusion and exclusion criteria. Research units are allocated into two intervention and control groups using simple randomization online, by the sequence created at www.graphpad.com/quickcalcs; The Equisetum arvense (horse tail) and placebo cream, prepared and packaged by a pharmacy advisor professor at the Pharmacological Research Center of Medicinal Plants of Mashhad University of Medical Sciences. the pharmacy advisor professor has assigned a code to each group(only the Pharmacy Advisor professor knows it). Based on the A and B codes assigned to the two groups, the sequence is exemplified AABAB... . In order to allocation concealment, opaque, sealed and in sequentially numbered envelopes will be used that are kept by the secretary of obstetric clinic.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In order to blinding, the Equisetum arvense (horse tail) and placebo cream are provided to the researcher in similar shapes and identical tubes. Each tube has a code that only the pharmacy consultant professor knows about it. Individuals with inclusion criteria are grouped into intervention and control groups according to the sequence based on the codes; and by the end of the study, research units, the researcher, the statistical analyzer and delivery agent will not know about the codes of Equisetum arvense and placebo cream.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Assistance of Research and Technology of Mashhad University of Medical Sciences, Qurashi building, Daneshgah avenue

City
Mashhad

Province
Razavi Khorasan

Postal code
91388-13944

Approval date
2020-01-27, 1398/11/07

Ethics committee reference number
IR.MUMS.NURSE.REC.1398.101

Health conditions studied

1

Description of health condition studied
Perineal laceration during delivery

ICD-10 code
O70

ICD-10 code description
Perineal laceration during delivery

Primary outcomes

1

Description
Perineal laceration degree

Timepoint
Immediately after delivery

Method of measurement
Observation

2

Description
perineal laceration length
Timepoint
Immediately after delivery
Method of measurement
Measuring with sterile swap and ruler

3

Description
perineal laceration depth
Timepoint
Immediately after delivery
Method of measurement
Measuring with sterile swap and ruler

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Individuals in intervention group will apply a knuckle of equisetum arvense cream 3%(which is made in Pharmacological Research Center of Medicinal Plants of Mashhad University of Medical Sciences) in the perineum and the beginning part of vagina by the thumb and forefinger with a reciprocal movement,once at night before sleeping, from the beginning of 37-38 weeks of gestation. This group will receive routine midwifery care until delivery; episiotomy will be performed at delivery time, if indicated, on the discretion of the delivery agent.
Category
Prevention

2

Description
Control group: Individuals in control group will apply a knuckle of cold cream (moisturizing cream, which is made in Pharmacological Research Center of Medicinal Plants of Mashhad University of Medical Sciences) in the perineum and the beginning part of vagina by the thumb and forefinger with a reciprocal movement,once at night before sleeping, from the beginning of 37-38 weeks of gestation. This group will receive routine midwifery care until delivery; episiotomy will be performed at delivery time, if indicated, on the discretion of the delivery agent.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Omolbanin hospital
Full name of responsible person
Farideh Akhlaghi
Street address
Omolbanin hospital, Ayatollah Bahjat 16, Ayatollah Bahjat Ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3223 1061
Fax
+98 51 3223 1444
Email
AkhlaghiF@mums.ac.ir
Web page address
https://woman.mums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Assistance of Research and Technology of Mashhad University of Medical Sciences, Qurashi building, Daneshgah avenue
City
Mashhad
Province
Razavi Khorasan
Postal code
917751365
Phone
+98 51 3882 3255
Email
Tafaghodim@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

Fatemeh Khademolkhamseh

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Mashhad College of nursing and midwifery, Ibn Sina Ave., Doctora intersection, Daneshgah Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

Khademkf971@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Samira Ebrahimzadeh Zagami

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Mashhad College of nursing and midwifery, Ibn Sina Ave., Doctora intersection, Daneshgah Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

EbrahimzadehZS@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Khademolkhamseh

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Mashhad College of nursing and midwifery, Ibn Sina Ave., Doctora intersection, Daneshgah Ave.

City

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Province

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Postal code

9137913199

Phone

+98 51 3859 1511

Email

Khademkf971@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