Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of achillea flowers cream compared to routin care (betadin) on healing of episiotomy in primiparous women: a randomized clinical trial

Protocol summary

Summary

This study aimed to investigate the effect of yarrow flowers cream compared with povidone-iodine solution, on the healing process of episiotomy wounds. This study is a randomized clinical trial. Women who give birth in Emam Khomeini hospital and have episiotomy will be allocated randomly (lottery) in the intervention and intervention groups. Inclusion criteria would be primary par women with Natural delivery and Medio lateral episiotomy. In the intervention group, patients will treat with yarrow cream; thus the site of sutures will cover with the cream twice a day (for ten Days). The control group will use the routine care (Betadine solution). Wound healing will be evaluated using REEDA in seventh and tenth days after delivery. For double-blinding, prescription of drug will be done by one of the researchers and wound healing will be assessed by fellow midwives and data analysis will be done by someone else. We will use the chi-square test, Mann-Whitney, t-test and repeated measures to analysis the data.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017053134261N1**
Registration date: **2017-08-10, 1396/05/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-10, 1396/05/19

Registrant information

Name

Azam Rahmani

Name of organization / entity

Nursing and Midwifery Care Research Center, Tehran University of Medical Sciences, Tehran, Iran.

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4566

Email address

arahmani@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of achillea flowers cream compared to routin care (betadin) on healing of episiotomy in primiparous women: a randomized clinical trial

Public title

The effect of yarrow flowers cream on healing of episiotomy in primiparous women: a randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:primary par women; natural delivery with medio lateral episiotomy; living with her husband; absence of diseases disturbing wound healing (such as chronic systemic diseases, heart, kidney, liver,

respiratory, coagulation, tissue, diabetes, anemia, cancer and mental illness); absence of using drugs affecting wound healing (such as glucocorticoids, anticoagulants, immunosuppressant, antibiotics and chemotherapy drugs); single fetus with anterior cephalic presentation; absence of symptomatic infection of the vagina and vulva (infectious discharge, itching and burning sensation); no obvious abnormalities in infants (hydrocephalus, ascites, a huge mass in the body); no Rectocele and severe Cystocels (grade 2 and above) or vaginal mass; no history of obstetric problems (placenta previa, placental abruption, multiple pregnancy, polyhydramnios, oligohydramnios, conflict RH, rupture of the membranes more than 12 hours); BMI in limited 19/8-30 kilograms per square meter; absence of reconstructive surgery on the vagina and perineum. Exclusion criteria: Disordering in the progress of labor (fast delivery and prolonged labor); lasted the second stage of labor more than 2 hours; extending the incision and converting into the 3rd and 4th degree tears or extending tears other than episiotomy; abnormal vaginal bleeding (abnormal vaginal bleeding that requires further evaluation by valve); shoulder dystocia that led to the use of non-Mac Robert maneuvers; Placental withdrawal by hand.

Age
No age limit

Gender
Female

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Nursing and Midwifery faculty, Tehran University of Medical Sciences

Street address
Nursing and Midwifery University, Mirkhani Street,Towhid Square

City
Tehran

Postal code

Approval date
2017-05-07, 1396/02/17

Ethics committee reference number
IR.TUMS.FNM.REC.1396.2245

Health conditions studied

1

Description of health condition studied
Wound Healing

ICD-10 code
o90.1

ICD-10 code description
Disruption of perineal obstetric wound

Primary outcomes

1

Description
wound healing

Timepoint
1th, 7th and 10th day after intervention

Method of measurement
REEDA

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, patients will treat with yarrow cream; thus the site of sutures will cover with the cream (1.5 percent) twice a day (for ten Days).

Category
Treatment - Drugs

2

Description
The control group will be placed under routine care (iodine solution). The diluted solution will be made up and used twice a day (for ten days) by patients.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Khomeini hospital

Full name of responsible person

Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy of Tehran University of Medical Sciences
Full name of responsible person
Mis Kardan Moghaddam
Street address
Central Building of Tehran University of Medical Sciences, Ghods Street, Keshavarz Bolvar, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy of Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ms KArdan-moghaddam
Position
Research expert
Other areas of specialty/work
Street address
Central Building of Tehran University of Medical Sciences, Ghods Street, Keshavrz Bolvar, Tehran.
City
Tehran
Postal code
Phone
+98 21 8163 3605
Fax
Email
azamrahmani7@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Azam Rahmani
Position
PhD
Other areas of specialty/work
Street address
Nursing and Midwifery care research center, Tehran faculty of Nursing and Midwifery, Mirkhani street, Towhid Square, Tehran
City
Tehran
Postal code
Phone
+98 21 6105 4566
Fax
Email
arahmai!@sina.tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Nursing and Midwifery Care Research Center, Tehran University of Medical Sciences, Tehran, Iran.
Full name of responsible person
Azam Rahmani
Position
Assisstant Professor/ PhD
Other areas of specialty/work
Street address
Nursing and Midwifery care research center, Tehran faculty of Nursing and Midwifery, Mirkhani street, Towhid Square, Tehran
City
Tehran
Postal code
Phone
+98 21 6105 4566
Fax
Email
arahmani@sina.tums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code

empty

Data Dictionary

empty