Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of normal saline with Betadine solution in episiotomy wound healing

Protocol summary

Summary
The objective of this study was to compare normal saline and Betadine solution in episiotomy wound healing. This study was a randomized controlled trial, in which 120 nuliparous or multiparous women with episiotomy were randomly assigned into intervention or control group. For the patients in the intervention group, 10cc normal saline, 9 in 1000 cc, was sprinkled on episiotomy wound by a sterile syringe, three times a day for ten days. In the control group, 10% povidone iodine solution, three tablespoons in four glasses of water three times a day, was used similarly as the normal saline. Episiotomy wound were checked based on the standard REEDA checklist (erythema, edema, ecchymosis, and wound secretion) on the fifth and tenth day after episiotomy.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT201012221839N3**
Registration date: **2011-01-08, 1389/10/18**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2011-01-08, 1389/10/18

Registrant information
Name
Mahtab Attarha
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Arak University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source
Vice Chancellor for Research of Arak University Medical Sciences

Expected recruitment start date
2009-07-23, 1388/05/01
Expected recruitment end date
2010-02-23, 1388/12/04
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of normal saline with Betadine solution in episiotomy wound healing

Public title
Episiotomy wound healing
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: full term pregnancy, singelton pregnancy with normal vaginal delivery, spontaneous placenta removal, PROM less than 18 hours, no illnesses that affect wound healing such as: cardiac, pulmonary, kidney disease, diabetes, anemia, coagolopathy and malnutrition Exclusion criteria: require to any antibiotics or immunosuppressive drugs during the study, change in location, not coming on the examination date and cases have not been instructed the plan of study
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single 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 Arak University Medical Sciences
Street address
Second Floor of Education Department Building, Pardis Building Complex, Arak University Medical Sciences, Sardasht Sq.
City
Arak
Postal code
76941-38481
Approval date
2009-07-23, 1388/05/01
Ethics committee reference number
4-60-88

Health conditions studied

1

Description of health condition studied
Episiotomy Wound Healing
ICD-10 code
O00, O99
ICD-10 code description
Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
Episiotomy wound healing
Timepoint
The third, seventh and tenth days during treatment
Method of measurement
Rate of healing

Secondary outcomes

1

Description
Edema, inflammation and redness
Timepoint
The third, seventh and tenth during treatment
Method of measurement
Reeda score

Intervention groups

1

Description
Intervention group: 10 cc saline normal (9 in 1000 cc), manufactured by Samen Pharmaceutical Co., was sprinkled on episiotomy wound by a sterile syringe, three times a day for ten days
Category
Treatment - Drugs

2

Description
Control group: 10 cc povidone iodine solution 10%, three tablespoons in four glasses of water, manufactured by Samen Pharmaceutical Co., was sprinkled on episiotomy wound by a sterile syringe, three times a day for ten days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Educational and Treatment Center of Ayatollah Taleghani
Full name of responsible person
Mahtab Attarha
Street address
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Arak University Medical Sciences
Full name of responsible person
Davood Hekmat Poo
Street address

Second Floor of Education Department Building, Pardis Building Complex, Arak University Medical Sciences, Sardasht Sq.

City
Arak

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice Chancellor for Research of Arak University 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
Nursing and Midwifery Faculty of Arak University Medical Sciences

Full name of responsible person
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Position
Istractor, academician

Other areas of specialty/work

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Postal code

Phone

Fax

Email

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