Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of Alfa ointment and Betadin solution on wound healing of episiotomy in primiparous women

Protocol summary

Summary

Episiotomy cutting perineal muscles, with the aim of accelerating the completion of to improve the outcome for mother and baby. Drugs with anti-inflammatory effects, antibacterial activity are suitable for wound healing. Alfa ointment has all of the above. The objective of this study, is to compare Alfa ointment and povidon Iodine solution (Betadin) on wound healing episiotomy. This study is single blind 140 women admitted to hospital Kamali Karaj ,Iran. Nulliparous women aged 18-45 years, cephalic, no history of disease impaired wound healing and not using drugs effecting on wound healing. Samples of available with easy method and using a randomized design with two groups (control group: sitz bath with Povidon Iodine) and (intervention group: sitz bath with Povidone Iodine in addition Alfa ointment). The labor process control and information related to this process. A disruption in the process of labor, delivery devices (vaccum, forceps) have extended, or there was lengh tear except episiotomy tear, the research unit would excluded. Unit of study of prescribed sitz bath with povidon iodine 3times daily for 7 days.Intervention group using Alfa ointment 3times daily for 7 days, placed on the sutures. Episiotomy wound were checked based on the checklist standard REEDA on first, third and seventh days after delivery. Pain of episiotomy, were checked based on the Mac Gill pain router on first, third and seventh days after delivery by the researcher.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071523230N1**
Registration date: **2015-09-24, 1394/07/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-09-24, 1394/07/02

Registrant information

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Peimaneh Naghdi Dorbati
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Recruitment status

Recruitment complete

Funding source

Alborz University Of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Alfa ointment and Betadin solution on wound healing of episiotomy in primiparous women

Public title

Wound Healing of Episiotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: primiparous; literate; Iranian; BMI

prenatal 19.8_26; no history of disease chronic; liver; renal; diabetes; coagulation disease; anemia; constipation; hemorrhoids; no surgery; no taking anti coagulation; anti epileptic; anti depressants; alcohol; smoking drug; no having active skin disease; allergic disorder; symptomatic vaginitis; wound in place or skin sensitivity; Cephalic presentation; anterior position; lack of long term rapture of membrane (less than 18h) ; first stage for delivery less than14h; second stage for delivery less than 2h; third stage for delivery less than 1h; delivery on pregnancy bed prepared and drp; no grade3 and 4tear; repair of episiotomy using Chromic suture Catgut 0 and 2/0 using the same; episiotomy repaired time less than 25minutes. Exclusion criteria: allergy; no using drugs.

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **140**

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
Alborz University of Medical Sciences

Street address
Administrative town, above the right Taleghani, Taleghani Blvd

City
Karaj

Postal code

Approval date
2015-06-17, 1394/03/27

Ethics committee reference number
abzums.rec1394.19

Health conditions studied

1

Description of health condition studied
Wound healing of episiotomy

ICD-10 code
000-099

ICD-10 code description
Pregnancy,Child birth and the puerperium

Primary outcomes

1

Description
Wound healing of episiotomy

Timepoint
First, third and seventh day after delivery during treatment

Method of measurement
Rate of healing (REEDA scale)

Secondary outcomes

1

Description
Pain of episiotomy

Timepoint
First, third and seventh day after delivery during threatment

Method of measurement
McGill pain Questionnaire short

Intervention groups

1

Description
Intervention group: use the same protocol Povidon Iodine as sitz bath (30cc Povidon Iodine in 3litre of water) three times a day for seven days, intravenous antibiotic single dose (Cefazolin 2gr) ,Mefenamic Acid capsule 250 mg three times a day for three days ,inaddition Alfa ointment three times a day for seven days (each time a knuckle ointment is placed on the sutures so that the wound is completly coveres)

Category
Treatment - Drugs

2

Description
Control group: use the same protocol Povidon Iodine as sitz bath (30 cc Povidon Iodine in 3 litre of water) three times a day for seven days, intravenous antibiotic single dose (Cefazolin 2 gr) , Mefenamic Acid capsoule 250 mg three times a day for three days.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Educational and Treatment Center of Kamali
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz University of Medical Sciences
Full name of responsible person
Dr. Drafshi
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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
Alborz 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

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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