Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison Between Commiphora Myrrh, Boswellia Spp. And Betadine Solution For Repair of Episiotomy After Normal Vaginal Delivery

Protocol summary

Study aim
Evaluate the effect of Boswellia spp. and Commiphora Myrrh and comparing them with betadine solution on repair of the episiotomy wound after normal vaginal delivery, with regard to "REEDA" questionnaire.

Design
This is a double-blinded study.90 patients are enrolled in the study. They were divided into three groups accidentally the herbal formulations and also povidone iodine were used as sitz bath twice daily for a week and participants were visited on the o, 2 and 7 day after delivery. REEDA questionnaire have been used to evaluate wound healing.

Settings and conduct
This study for evaluate the effect of Myrrh and Boswellia spp.on episiotomy wound healing and compariing it with betadine solution in Hafez and Zeinabie hospital was done. Formulation A, B and C have been administered in the similar bottles, so patients and researchers were unable to detect. Our nurse colleague in this study delivered formulations to the participants of the study according to the randomized block table. At the end of the study, the formulations were decoded and the patients assigned to each group were identified.

Participants/Inclusion and exclusion criteria
Inclusion criteria: NVD with mediolateral episiotomy; parity 1; normal BMI before pregnancy< 25 ; GA 37 to 42 wks; Available for several post-partum visits Exclusion Criteria: complications immediately after delivery; instrumental delivery; 3º or 4º degree perineal laceration; who have history of medical problems like diabetes mellitus...; Previous history of perineorrhaphy; perineal hematoma; post-delivery fever > 38; smokers; infection of the episiotomy site; prolonged rupture of membranes

Intervention groups
Group intervention 1 received herbal formulation based on Myrrh, group intervention 2 herbal formulation based on Boswellia and control group Betadine solution.

Main outcome variables
Wound healing

General information

Reason for update
Recording errors

Acronym

IRCT registration information
IRCT registration number: **IRCT20140525017827N5**
Registration date: **2019-07-28, 1398/05/06**
Registration timing: **prospective**

Last update: **2019-12-23, 1398/10/02**
Update count: **3**

Registration date
2019-07-28, 1398/05/06

Registrant information

Name
Nasrin Asadi

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 71 1233 2365

Email address
asadin@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-29, 1398/05/07

Expected recruitment end date
2019-10-12, 1398/07/20

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison Between Commiphora Myrrh, Boswellia Spp. And Betadine Solution For Repair of Episiotomy After Normal Vaginal Delivery

Public title
Comparison Between Myrrh, Boswellia And Betadine For Repair of Episiotomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Who have normal vaginal delivery with mediolateral episiotomy. parity 1 Normal body mass index (BMI) before pregnancy (less than 25). Gestational age 37 to 42 weeks Available for several post partum visits
Exclusion criteria:
Mothers who have complications immediately after devilry instrumental delivery 3º or 4º degree perineal laceration who have history of medical problems like diabetes mellitus, hypertention, anemia, Rheumatology disease... Previous history of perineorrhaphy perineal hematoma post delivery fever upper than 38 degree of centigrade smokers infection of the episiotomy site prolonged rupture of membranes
Age
From **18 years** old to **41 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Formulation A, B and C have been administered in the similar bottles, are made by the pharmacists with the same appearance and characteristics and will be given to our colleague drug distributor in the form of A or B or C. The treatment allocation list is already designed on Block Balanced Randomization Method by the computer software. 1 (A), 2 (B), 3 (B), 4 (B), 5 (A),..... Any eligible patient will be given a 1 to 90 code after obtaining informed consent in order to visit the clinic and based on above block, they receive A or B or C drug. The drug distributor doesn’t have a role in the treatment plan and data analysis. The patients, researcher, data analyzer are not aware of the type of treatment for each patient. Finally, the patients will be followed by their own codes
Blinding (investigator's opinion)
Double blinded
Blinding description
Formulation A, B and C have been administered in the similar bottles, so patients and researchers were unable to detect which one was Myrrh, Boswelia and betadine. Our nurse colleague in this study in Hafez and Zeinabie hospitals delivered formulations to the participants of the study according to the randomized block table. She was unaware of the content of the bottles. The researcher had no information about formulation used by each patient while visiting them. At the end of the study, the formulations were decoded and the patients assigned to each group were identified.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Headquarters Of Shiraz University of Medical Sciences, Zand St, Shiraz
City
Shiraz
Province
Fars
Postal code
34786-71946
Approval date
2019-02-27, 1397/12/08
Ethics committee reference number
IR.SUMS.MED.REC.1398.001

Health conditions studied

1

Description of health condition studied
Episiotomy wound healing
ICD-10 code
O90.1
ICD-10 code description
Disruption of perineal obstetric wound

Primary outcomes

1

Description

wound healing

Timepoint

The 0, 2 , 7 day after delivery

Method of measurement

visiting the paients and filling " REEDA" questionnaire by the researcher

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A will receive herbal formulation based on Myrrh, Hydro alcoholic extract of Myrrh resin prepared by 1: 5 ratio (90% ethanol was used). Each patient will use 15 cc in 5 liter of water for 10 minutes, twice a day for a week.

Category

Treatment - Drugs

2

Description

Intervention group: Group B will receive herbal formulation based on Boswellia, Hydro alcoholic extract of Boswellia resin prepared by 1: 5 ratio (90% ethanol was used). Each patient will use 15 cc in 5 liter of water for 10 minutes, twice daily for a week.

Category

Treatment - Drugs

3

Description

Control group: Patients in group C will use Betadine solution, 15 cc in 5 liter of water for 10 minutes, twice daily for a week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghehi Hospital affiliated to Shiraz University of Medical Science

Full name of responsible person

Marym Aghdaki

Street address

Shahid Faghehi Hospital, Zand blvd

City

Shiraz

Province

Fars

Postal code

71848-37786

Phone

+98 71 3233 2365

Email

maryam.aghdaki@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Yoones Ghasemi

Street address

Building of Shiraz University of Medical Sciences, Zand Ave

City

Shiraz

Province

Fars

Postal code

34786-71946

Phone

+98 71 3235 7282

Email

ghasemiy@sums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Shiraz University Of medical Science

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

Shiraz University of Medical Sciences

Full name of responsible person

Marya Aghdaki

Position

Resident of obstetrics and gynecology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City
Shiraz
Province
Fars
Postal code
34786-71946
Phone
+98 71 3233 2365
Email
maryam.aghdaki@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Nasrin Asadi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Maternal- Fetal Medicine (Perinatology), Hafez Hospital, Chamran Ave., Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
34786-71946
Phone
+98 71 3612 8258
Email
nsasadi2002@yahoo.ca

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Nasrin Asadi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Maternal- Fetal Medicine (Perinatology), Hafez Hospital, Chamran Ave., Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
34786-71946
Phone
+98 71 3612 8257
Email
nasadi2012@yahoo.ca

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable
Informed Consent Form
Yes - There is 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
Title and more details about the data/document
En IPD: Information and research data Ethic form: Complete the Ethic form by the patient
When the data will become available and for how long
IPD: 2019 Ethic form: 2019
To whom data/document is available
IPD: Researcher & Patient Ethic form: Patient
Under which criteria data/document could be used
IPD: Ethic form: Awareness of test results
From where data/document is obtainable
IPD: OB & Gyn ward Shiraz university of medical sciences Ethic form: OB & Gyn ward Shiraz university of medical sciences
What processes are involved for a request to access data/document
IPD: Vice chancellery Ethic form: Vice chancellery
Comments