

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Determining the effect of Rosa canina capsules on the incidence of urinary tract infection in the puerperium: a randomized controlled trial

Protocol summary

Summary

Objectives: To determine the effect of Rosa canina capsules on the incidence of urinary tract infection in the puerperal period in women have C-section. **Design:** Two-arm, randomized, triple-blind, controlled trial (the assessor, participants, and data analyser will be unaware of the type of intervention given to every participant). **Conduct:** This trial will be conducted on 400 women (200 in each group) hospitalized after cesarean delivery in Alzahra and Taleghani therapeutic and educational centers in Tabriz. After obtaining written informed consent from eligible individuals, urine samples will be taken for urine culture. If they do not have asymptomatic bacteriuria, they will be enrolled in the study. Participants will be randomly assigned to two groups of intervention (receiving Rosa canina capsules) and control (receiving placebo) using block randomization with block sizes of 4 and 6 the allocation ratio of 1:1. **Participants:** Delivered women by cesarean section with a catheter in the past 48 hours. **Intervention:** The intervention group will receive two capsules containing Rosa canina and the control group will receive two capsules containing starch (placebo) daily from 48 hours to 20 days after cesarean section. The main outcome variable include incidence rate of urinary tract infection during 20 days after a cesarean section. The secondary outcome variables include the incidence rate of asymptomatic bacteriuria in 7-10 days and 20 days after cesarean section and incidence rate of cystitis and pyelonephritis during 20 days after cesarean section.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040910324N30**
Registration date: **2016-08-28, 1395/06/07**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-08-28, 1395/06/07

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-09-10, 1395/06/20

Expected recruitment end date

2017-01-09, 1395/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effect of Rosa canina capsules on the incidence of urinary tract infection in the puerperium: a randomized controlled trial

Public title

Determining the effect of Rosa canina capsules on the incidence of urinary tract infection in the puerperium

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Having a cesarean section in the last 48 hours; Taking of three doses of antibiotics after surgery; Having willingness to participate in the study; Having phone number for follow-up; Not participate in other similar studies. Exclusion criteria: Having symptoms of urinary tract infections; Specific conditions that need to take antibiotics after discharge; Using of immunosuppressive drugs and related drugs to the respiratory system; Lack of catheterization during cesarean section

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **400**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East azerbaijan

City

Tabriz

Postal code

Approval date

2016-06-20, 1395/03/31

Ethics committee reference number

IR.TBZMED.REC.1395.231

Health conditions studied

1

Description of health condition studied

Urinary tract infection following delivery

ICD-10 code

O86.2

ICD-10 code description

Urinary tract infection following delivery

Primary outcomes

1

Description

The incidence of urinary tract infection (UTI)

Timepoint

7-10 and 20 days after cesarean section

Method of measurement

Urine culture and checklist of urinary infection symptoms

Secondary outcomes

1

Description

Side events

Timepoint

During the study

Method of measurement

Checklist of side events

2

Description

The incidence of pyelonephritis

Timepoint

During 20 days after cesarean

Method of measurement

Urine culture and checklist of urinary infection symptoms

3

Description

The incidence of cystitis

Timepoint

During 20 days after cesarean

Method of measurement

Urine culture and checklist of urinary infection symptoms

4

Description

The incidence of asymptomatic bacteriuria

Timepoint

7-10 days and 20 days after cesarean

Method of measurement

Urine culture

Intervention groups

1

Description

The intervention group will receive two capsules of 500 mg Rosa canina daily ½ hours after two meals (breakfast and dinner) orally with a full glass of water for 18 days.

Category

Treatment - Drugs

2

Description

The intervention group will receive two capsules of 500 mg placebo (containing starch) daily ½ hours after two meals (breakfast and dinner) orally with a full glass of water for 18 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

AlzahraTherapeutic Educational Center

Full name of responsible person

Mahdieh Seifi

Street address

Baghshmal intersection, South army street, Tabriz

City

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2

Recruitment center

Name of recruitment center

Talegani Therapeutic Educational Center

Full name of responsible person

Mahdieh Seifi

Street address

Railway Square, 22 Bahman street, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Reza Rashidi

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Tabriz

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, Tabriz 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

Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

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Position

MSc Student of Midwifery

Other areas of specialty/work

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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