# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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
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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 Univercity 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**
Tabriz

### 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
**City**
Tabriz

## 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
**Street address**
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan
**City**
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**
Mahdieh Seifi
**Position**
MSc Student of Midwifery
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*