Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effects of vitamin E on the treatment and prevention of relapse in women with lower urinary tract infection

Protocol summary

Study aim
Determination of the effect of vitamin E on the treatment and prevention of relapse in women with lower urinary tract infection

Design
Clinical trial with control group, double-blind, randomized, phase 3 on 80 women with lower urinary tract infection. In this study, individuals will be assigned to intervention and control groups by lottery randomization method.

Settings and conduct
This clinical trial will be performed on 80 women with lower urinary tract infections over 18 years of age referred to the Infectious Clinic of Vali-e-Asr Hospital in Birjand. All of the steps will be covered by the patient, physician and evaluators.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women over 18 years, At least three symptoms including frequency, urgency (urgent need to urinate), dysuria, hematuria, and suprapubic pain
Exclusion criteria: History of allergy or intolerance to vitamin E, Peptic ulcer bleeding, Hemophilia, Use of antiplatelet and anticoagulant drugs, Urinary tract obstruction and urological abnormalities, History of renal abscess, Diabetes mellitus, Taking antibiotics in the previous two days, Catheterization two weeks ago, History of hospitalization or catheter in two weeks ago, Kidney stones, Pregnancy and lactation, Immune deficiency (Patients with HIV, etc), Vitamin K deficiency, Liver and renal failure, Candidate for surgery, Flank pain, fever above 37.7 ° C, fever and chills, feeling ill and tired or other evidence of systemic infection, CVA tenderness, symptoms of vaginitis (itching and vaginal discharge)

Intervention groups
Intervention group: Vitamin E softgel 100 units daily for 6 months Control group: Vitamin E softgel placebo 100 units daily for 6 months

Main outcome variables
Frequency, Dysuria, Urgency, Recurrence rate of urinary tract infection, Mean recovery time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210617051604N1**
Registration date: **2021-07-11, 1400/04/20**
Registration timing: **prospective**

Last update: **2021-07-11, 1400/04/20**
Update count: **0**

Registration date
2021-07-11, 1400/04/20

Registrant information

Name
Razieh Avan

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 56 3238 1925

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2022-07-23, 1401/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effects of vitamin E on the treatment and prevention of relapse in women with lower urinary tract infection

Public title
Evaluation of the effect of vitamin E in women with urinary tract infection

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women over 18 years At least three symptoms including frequency, urgency (urgent need to urinate), dysuria, hematuria, and suprapubic pain

Exclusion criteria:
History of allergy or intolerance to vitamin E Peptic ulcer bleeding Hemophilia Use of antiplatelet and anticoagulant drugs Urinary tract obstruction and urological abnormalities History of renal abscess Diabetes mellitus Taking antibiotics in the previous two days Catheterization two weeks ago History of hospitalization or catheter in two weeks ago Kidney stones Pregnancy and lactation Immune deficiency (Patients with HIV, etc) Vitamin K deficiency Liver and renal failure Candidate for surgery Flank pain, fever above 37.7 ° C, fever and chills, feeling ill and tired or other evidence of systemic infection, CVA tenderness, symptoms of vaginitis (itching and vaginal discharge)

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly divided into two groups using a random number table. First, we create a variable from 1 to 80 in Excel software. Then we create another variable in another column and generate 40 random numbers one and 40 random numbers two with the randomization command. The numbers of one and two are intervention and placebo groups, respectively.

Blinding (investigator's opinion)
Double blinded

Blinding description
All of the steps will be covered by the patient, physician and evaluators.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Birjand University of Medical Sciences

Street address
Birjand University of Medical Sciences, Ghaffari Street

City
Birjand

Province
South Khorasan

Postal code
9717853577

Approval date
2020-09-28, 1399/07/07

Ethics committee reference number
IR.BUMS.REC.1399.303

Health conditions studied

1

Description of health condition studied
Lower urinary tract infection

ICD-10 code
N39.0

ICD-10 code description
Urinary tract infection, site not specified

Primary outcomes

1

Description
Frequency

Timepoint
3 to 5 days after starting treatment

Method of measurement
Questionnaire

2

Description
Dysuria

Timepoint
3 to 5 days after starting treatment

Method of measurement
Questionnaire

3

Description

Urgency

Timepoint

3 to 5 days after starting treatment

Method of measurement

Questionnaire

4

Description

Recurrence rate of urinary tract infection

Timepoint

3 and 6 months after starting treatment

Method of measurement

Questionnaire

5

Description

Mean recovery time

Timepoint

During study

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Vitamin E softgel 100 units daily for 6 months

Category

Treatment - Drugs

2

Description

Control group: Vitamin E softgel placebo 100 units daily for 6 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-e-Asr Educational and Medical Center affiliated to Birjand University of Medical Sciences

Full name of responsible person

Azadeh Ebrahimzadeh

Street address

Ghaffari Street, Vali-e-Asr Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Deputy of research and technology, Birjand University of Medical Sciences

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research@bums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand University of Medical Sciences

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

Birjand University of Medical Sciences

Full name of responsible person

Hajar Mafakher

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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