

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the therapeutic effect of honey vaginal jel with clotrimazole vaginal cream for treatment of vol vovaginit candidasis

Protocol summary

Summary

Background: Vaginitis is the commonest reason for gynecological consultation in women of childbearing age. Due to the side effect of chemical drugs try to find safe drug with more effect is one of the treatment purposes. Honey is a curative element in herbal extracts has various applications which it is anti-fungal property has been proved. This study was carried out to compare to therapeutic effect of honey vaginal jel with clotrimazole vaginal cream for treatment of volvovaginit candidiasis. Methods: This study was a single-blind randomized clinical trial that conducted on 106 patients at fertility age for three steps. From the viewpoint of clinical complaints and laboratory culture. All the patients were diagnosed to be affected and underwent treatment in two groups of 53 individuals each with clotrimazole and honey randomly. The results were compared after 8 days of therapy and reculturing. a p-value of <0.05 was considered statistically significant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604144317N9**
Registration date: **2016-06-28, 1395/04/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-28, 1395/04/08

Registrant information

Name

Fatemeh Nahidi

Name of organization / entity

Shahid Beheshti University of Medical Sciences and

Health Services

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effect of honey vaginal jel with clotrimazole vaginal cream for treatment of vol vovaginit candidasis

Public title

Comparison of the therapeutic effect of honey vaginal jel with clotrimazole vaginal cream for treatment of vol vovaginit candidasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: non-pregnant women who had not used immune suppressors, or broad spectrum antibiotics in the last month, and had no history of epilepsy, diabetes, cardiac diseases, hypertension, thyroid diseases, or advanced arthritis.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences-
International Branch

Street address

Shahid Beheshti University of Medical Sciences,
Beside Hemat Bridge, Shahid Abbaspour Avenue, Vali
Asr Avenue

City

Tehran

Postal code

Approval date

2015-01-05, 1393/10/15

Ethics committee reference number

1000/2577

Health conditions studied

1

Description of health condition studied

Vulvovaginal candidiasis

ICD-10 code

N77.1

ICD-10 code description

Candidiasis of vulva and vagina

Primary outcomes

1

Description

Vaginal discharge

Timepoint

First, 4th and 8th day after treatment

Method of measurement

Self- making questionnaire

Secondary outcomes

1

Description

Vaginal irradiation

Timepoint

First, 4th and 8th day after treatment

Method of measurement

Self- making questionnaire

2

Description

Itching

Timepoint

First, 4th and 8th day after treatment

Method of measurement

Self- making questionnaire

Intervention groups

1

Description

In intervention group Honey vaginal gel for 8 days

Category

Treatment - Drugs

2

Description

lin control group clotrimazole vaginal cream for 8 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences Shahriyar
Health Center

Full name of responsible person

Zahra Seifinadergoli

Street address

Number 36, Saba St., Tohid Avenue, Yaghchian

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, 2nd SBUMS Bldg., Next to Ayatollah
Taleghani Hospital, Evin, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Department of Midwifery and Reproductive Health of
Shahid Beheshti University of Medical Sciences, F

Full name of responsible person

Nahid Fatemeh

Position

PhD, Head of Midwifery group

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