

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluating healing effect of honey sitz bath on erosions caused by colposcopy in patients with ASC-H in papsmear

Protocol summary

Study aim

Evaluate healing effect of honey on erosions caused by colposcopy and biopsy in ASC-H

Design

In this research, 60 patients referring to oncology clinic were chosen purposefully and a code was allocated to each one of them. Then, patients will be divided into two control and intervention groups depending on even/odd day.

Settings and conduct

This study evaluates healing effect of honey on erosions caused by colposcopy and biopsy in ASC-H at oncology clinic of Fatemieh hospital, Hamadan. Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

Participants/Inclusion and exclusion criteria

Including criteria: Papsmear ASC-H
Excluding criteria: Any immune deficiency; cigarette smoking; any chronic disease that interfere with wound healing such as DM; medication usage that interfere with wound healing: corticosteroids; anticoagulants immunosuppressant and chemotherapy.

Intervention groups

Intervention group: Patients who receive honey gel twice a day for one week
control group: Patients who receive placebo gel twice a day for one week

Main outcome variables

Healing of lesion caused by colposcopy and biopsy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161026030517N1**

Registration date: **2017-12-29, 1396/10/08**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-29, 1396/10/08**

Update count: **0**

Registration date

2017-12-29, 1396/10/08

Registrant information

Name

rahil askari nejad behzadi

Name of organization / entity

Hamedan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3648 4011

Email address

r.asgari@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2018-01-19, 1396/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating healing effect of honey sitz bath on erosions caused by colposcopy in patients with ASC-H in papsmear

Public title

healing effect of honey on erosions caused by colposcopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients referred for evaluation by colposcopy due to ASC-H in pap smear

Exclusion criteria:
Any immune deficiency; cigarette smoking; any chronic disease that interfere with wound healing such as DM; medication usage that interfere with wound healing: corticosteroids; anticoagulants immunosuppressant and chemotherapy.

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

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

Street address
Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code

6517838695

Approval date
2017-04-07, 1396/01/18

Ethics committee reference number
IR.UMSHA.REC.1396.36

Health conditions studied

1

Description of health condition studied
ASC-H

ICD-10 code
R87.611

ICD-10 code description
•Atypical squamous cells on cervical Papanicolaou smear cannot exclude high grade squamous intraepithelial lesion

Primary outcomes

1

Description
Healing of erosions caused by colposcopy

Timepoint
One and two weeks after treatment

Method of measurement
In weekly visits of patients; erosions are evaluated and the healing staging is done with qualitative measures: totally repaired; partially repaired; no change.

Secondary outcomes

1

Description
Evaluating erosion healing in case and control group

Timepoint
One and two weeks after treatment

Method of measurement
in 3 qualitative groups: totally repaired; partially repaired; no change.

2

Description
Evaluating cervical colposcopic status

Timepoint
First visit, one and two weeks after treatment

Method of measurement
With Reids colposcopic index: cervical intraepithelial neoplasia 1, 2, 3

Intervention groups

1

Description
In intervention group Doxycycline cap 100 mg PO bid given for 5 days; and honey gel 10% 10 cc vaginally

given for a week.
Category
Treatment - Drugs

2

Description
In control group Doxycycline cap 100 mg PO bid given for 5 days; and placebo gel 10 cc given for a week.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Dr Rahil Askari Nejad Behzadi
Street address
Fatemieh Hospital, Pasdaran Ave.
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Fatemieh@umsha.ac.ir
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid
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3253445642
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+98 81 3255 8801
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webda@umsha.ac.ir
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 the Technology, Hamadan
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
Fatemieh Hospital
Full name of responsible person
Rahil Askari Nejad Behzadi
Position
OB and GYN resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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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