Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

The effect of olive leaf extract and curcumin combination on improvement of clinical signs and symptoms and quality of life in patients with external anogenital wart

Protocol summary

Study aim

Determining the effect of combination of olive leaf extract and curcumin on improving clinical signs and symptoms and quality of life of patients with external anogenital warts

Design

Clinical trial with control group, three-way blind, randomized with randomized block.

Settings and conduct

The study is performed in the medical centers of the province with two groups of intervention and control by blinding the patient, the researcher and the analyzer using the coding of individuals, drugs and placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Confirmation and introduction of midwifery specialist Age 18 and up Lack of pregnancy and lactation The desire to participate in research and sign the informed consent Lack of incurable, metabolic and chronic diseases and weakness in the immune system Lack of pelvic inflammatory disease, other genital infectious diseases Do not use corticosteroids and antiviral drugs and weaken the immune system during research Failure to participate in other research that in any way affects the results of the research Phone access Exit criteria: Lack of proper and appropriate use of drugs Lack of desire to continue research Any allergies caused by the drug Failure to answer the phone Pregnancy Severe type of disease that requires surgery or systemic medication.

Intervention groups

Control group: Routine treatment with 20% pedophyllin once a week and the use of placebo (2 mm) 3 times a day until recovery for up to 12 weeks. Intervention group: Use of 20% pedophylline once a week and 10% olive leaf extract ointment and 10% curcumin (2 mm) 3 times a day until recovery for up to 12 weeks.

Main outcome variables

Clinical signs and symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200509047350N1**
Registration date: **2020-05-14, 1399/02/25**
Registration timing: **prospective**

Last update: **2020-05-14, 1399/02/25**
Update count: **0**

Registration date

2020-05-14, 1399/02/25

Registrant information

Name

Fateme Mehrabirad

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of olive leaf extract and curcumin combination on improvement of clinical signs and symptoms and quality of life in patients with external anogenital wart

Public title
The effect of olive leaf extract and curcumin combination on improvement of clinical signs and symptoms and quality of life in patients with external anogenital wart

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Confirmation and introduction of a midwifery specialist for the patient to enter the study (having external anogenital warts) Age 18 and up No pregnancy or lactation The desire to participate in research and sign a conscious consent Lack of incurable, metabolic and chronic diseases and weakness in the immune system Do not use corticosteroids or antiviral drugs and weaken the immune system during research Lack of pelvic inflammatory disease, other genital infectious diseases Failure to participate in other research that in any way affects the results of the research Phone access

Exclusion criteria:
Lack of proper and appropriate use of drugs Lack of desire to continue research Any allergies caused by the drug Disabling the patient or changing the patient's contact number and not answering the phone call Pregnancy Severe type of disease that requires surgery or systemic medication

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
Random block block The volume of each block is 4, so that 6 different combinations of 4 blocks are created and are selected randomly by placing the blocks.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, the Research Center codes the drug and placebo with specific and confidential codes. While using the patient, the researcher, the analyst, is not aware of the research groups (whether the patient has received the medication or the placebo) and is only in the groups with the medication codes they received. Finally, after analyzing the data, decryption is performed by the research center.

Placebo
Used

Assignment
Parallel

Other design features
Routine treatment in both groups means that on the first day of treatment, the midwife will first cover the wart with Vaseline cream containing vitamin E and then place a full swab soaked in pedophyllin 20% on the wart. The solution should be on the lesion for 4 hours and not washed under any circumstances. Before applying the ointment, a thin layer of the drug is placed on the inside of the forearm for 20 minutes and the redness, itching, burning, swelling and skin lesions will be examined. The lesion will be washed with water. Then the site of the lesion is dried and patients, according to the control groups and olive-curcumin leaf extract, apply 10% ointment to the lesions with a swab, and do not wash it until the next dose. This is done from the first day of treatment after pedophilia (once a week) for 3 times a day until complete recovery (maximum 12 weeks). The exact time and date of the start of treatment will be recorded by the researcher and the patient will be given the necessary training to take the medication. To receive pedophylline, the patient sees a specialist once a week, and the disease is examined and, if necessary, continued treatment. How to blind the study is done in such a way that the patient and the researcher and statistical analyst do not know how to divide people into groups. Each person will receive their own code and will be grouped into 1.2 groups using coding. Then, with the help of an obstetrician's examination, the treatment process is checked by observing privacy and the principle of confidentiality. The patient informs the researcher of the time of recovery of the lesions after the start of treatment as the exact time and date. The number of lesions before consumption, daily (at intervals of weekly visits by the patient), is examined and recorded every week by a midwife by direct observation according to the time of complete recovery after taking the medication. The quality of life questionnaire will be completed by the researcher before starting treatment and after complete recovery. The researcher will follow the patient from the first day of treatment until the next visit (once a week) using a mobile phone and contacting the patient (self-report), in terms of side effects (pain, bleeding, scaling, itching). It should be noted that the follow-up of drug use and washing by the subjects will be done by telephone by the researcher. Patients who may have a full recovery earlier than the due date should report the exact date and time of the recovery to the researcher during these calls.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Lorestan University of Medical Sciences

Street address

Lorestan University of Medical Sciences, Shahid Anoushirvan Rezaei Square, Moallem St.

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Approval date

2020-05-06, 1399/02/17

Ethics committee reference number

IR.LUMS.REC.1399.045

Health conditions studied

1

Description of health condition studied

Genital Warts

ICD-10 code

A63.0

ICD-10 code description

Anogenital (venereal) warts

Primary outcomes

1

Description

Clinical Signs and Symptoms: In this study, the clinical signs and symptoms of itching, burning, pain, warts and bleeding are considered.

Timepoint

Every week and the intervals between visits for a maximum of 12 weeks.

Method of measurement

clinical examination, self-report

Secondary outcomes

1

Description

Quality of Life

Timepoint

The day before treatment, after clinical repair

Method of measurement

Life Quality Questionnaire 36 questions SF36

Intervention groups

1

Description

Intervention group:Routine treatment with pedophile 20% once a week until clinical repair (maximum 12 weeks) and the use of 10% olive leaf extract ointment and 10% curcumin in the amount of 2 mm) (9 made by the University Health and Nutrition Research Center) Khorramabad Medical Sciences) 3 times a day until recovery (maximum 12 weeks). On the first day of treatment, the midwife will first cover the wart with a vitamin E-containing Vaseline cream and then place a full 20% pedophile -soaked swab on the wart. The solution should be on the lesion for 4 hours and not washed under any circumstances. Before applying the ointment, a thin layer of the drug is placed on the inside of the forearm for 20 minutes and the redness, itching, burning, swelling and skin lesions will be examined. The lesion will be washed with water. Then the site of the lesion is dried and the patients extract 10% of the ointment from the olive-curcumin leaf extract with a swab, and do not wash it until the next dose.

Category

Treatment - Drugs

2

Description

Control group: Routine treatment with pedophyllin 20% once a week until clinical repair (maximum 12 weeks) and the use of placebo (size 2 mm) (manufactured by Khorramabad University of Medical Sciences) 3 times a day until Recovery (maximum 12 weeks). On the first day of treatment, the midwife will first cover the wart with a vitamin E-containing Vaseline cream and then place a full 20% pedophyllin -soaked swab on the wart. The solution should be on the lesion for 4 hours and not washed under any circumstances. Before applying the ointment, a thin layer of placebo is placed on the inside of the forearm for 20 minutes to examine for redness, itching, burning, swelling, and skin lesions. The lesion will be washed with water. Then the site of the lesion is dried and the patients are given a placebo with a swab to the lesion, to avoid washing it until the next dose.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Midwifery Office

Full name of responsible person

Fateme Yari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Tahereh Toulabi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Tahereh Toulabi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Tahereh Toulabi

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Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
Information on the effect of the drug on primary and secondary outcomes.

When the data will become available and for how long
Start the access period 6 months after printing the results

To whom data/document is available
researchers

Under which criteria data/document could be used
Researchers first obtain permission from the researcher and refer to their research objectives to use any data or information.

From where data/document is obtainable
Postal address: Khorramabad, Lorestan University of Medical Sciences, Faculty of Nursing and Midwifery - Fatemeh Mehrabi Rad Contact Number: 00986633120140 Email: fatememehrabirad@gmail.com

What processes are involved for a request to access data/document
Dear researchers, you can ask your questions via email address Email: fatememehrabirad@gmail.com. We will answer your questions as soon as possible.

Comments