Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Nov 2026

Comparison of the effect of cream containing Green Tea Extract with Pedophilin solution in the treatment of Genital Warts in Women

Protocol summary

Study aim
The Comparison of the effect of cream containing Green Tea Extract with Pedophilin solution in the treatment of Genital Warts in Women

Design
Green tea extraction and cream preparation, sampling within 8 months, prescribing the cream after the diagnosis of lesions, follow up every two weeks until 12 weeks, determine the percentage of lesions recovery, statistical analysis

Settings and conduct
The present study is a one-stop clinical trial (statistical analyzer) that is performed on 80 women with foreign genital warts eligible for the study referred to the women's clinic of Hakim Shahrnishabour Hospital, who are classified into two groups by blocking and random allocation. . In the control group, pedophilin solution and in the intervention group are treated with green tea extract cream. Individuals will complete every 2 weeks of the visit and form.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Women with genital warts with 2 to 30 lesions, lesions between 2 and 600 mm cubic meters, genital warts are limited to skin, Exclusion criteria: are sensitive to the prescribed drug, the patient tends to continue to participate in the research Do not have to be pregnant during the study, if it does not use more than 20% of the drug per week.

Intervention groups
The intervention group received 10% green tea extract three times a day for 12 weeks or until complete recovery, the control group, pedophilin solution 10% once a week by the researcher for up to 6 weeks or until complete recovery

Main outcome variables
Reproductive rate of genital warts

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181114041652N1**
Registration date: **2019-05-26, 1398/03/05**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-26, 1398/03/05**
Update count: **0**

Registration date
2019-05-26, 1398/03/05

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-22, 1397/10/01

Expected recruitment end date
2019-08-23, 1398/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effect of cream containing Green Tea Extract with Pedophilin solution in the treatment of Genital Warts in Women

Public title

Comparison of the effect of cream containing Green Tea Extract with Pedophilin solution in the treatment of Genital Warts in Women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Have written consent to participate in the research, Iranians living in Neyshabur or Mashhad, Age from 18 to 50 years, have literacy to read and write, Do not pregnant and breastfeed,His wife has no other wife, No previous marriage history, There is no specific drug use his, Patient with immunodeficiency disease, There is no history of skin sensitization and skin diseases, Do not smoke, No other STI infections are present, Her husband does not have genital warts,Use condoms during treatment, The number of lesions is between 2 and 30 lesions, The level of waste is between 12 and 600 mm cubic meters, Genital warts are limited to the skin Her husband does not have genital warts اصلاح شد

Exclusion criteria:

It is susceptible to prescription. The patient does not want to continue to participate in the research،Pregnant during study, If it does not use more than 20% of the drug per week

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize, we use the blocking method 4 with blocks of constant volume of 4 in two groups A and B.If there are two therapies, there will be six different blocks for the four blocks: 1)TTCC 2) TCTC 3) TCCT 4) CCTT 5) CTCT 6) CTTC We create random numbers between 0 and 600 with computer help. For numbers between 0 and 100/6(TTCC), we count the numbers between 100/6 200/6 (TCTC) and ... and continue this until we reach the desired sample size.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, considering that the drug is a control group of the solution and the intervention group is cream, so there is no possibility of blinding the research units, also as the control group is prescribed by the researcher, there is no possibility of blinding for the researcher, so only the possibility of blind data analysis There is.

Placebo

Not used

Assignment

Parallel

Other design features

In the visits to follow up by the researcher, the measurements were made and the rate of reduction was lower than the initial size in percent and in each patient there were unwanted inflammatory reactions such as burning, itching, erythema, pain and erosion, as well as the severity of it during the course in the relevant form Registered by the researcher. In the absence of a complication, the score of zero, if there was a mild degree of any complication of score 1, in the mean intensity of score 2, and in case of severity of the 3rd, was attributed to each individual event. Patients treated by the researcher in three The scale is graded according to the percentage of reduction in lesions in terms of size and number indicating recovery rates. More than 91% (complete recovery), between 62 and 91% (moderate improvement), less than 62% (mild recovery).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad of Medical Science

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Quraishi Building، University Street، Mashhad

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Razavi Khorasan

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91735951

Approval date

2018-10-10, 1397/07/18

Ethics committee reference number

IR.MUMS.NURSE.REC.1397.046

Health conditions studied

1

Description of health condition studied

Genital warts

ICD-10 code

B07

ICD-10 code description

Anogenital (venereal) warts A63.0

Primary outcomes

1

Description

Percentage recovery of genital warts

Timepoint

At weeks 2, 4, 6, 8, 10, 12 after starting treatment

Method of measurement

The percentage of reduction in lesions is graded according to the dimensions and number indicating the rate of recovery of the lesions. More than 90% (complete recovery), between 65% and 90% (moderate improvement), less than 65% (mild recovery).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After the clinical diagnosis of lesions, in the intervention group, 10% cream of the green tea extract is performed three times a day for 12 weeks or until complete clearance. The cream is used by the patient at home and the patients are followed up by a researcher by phone one weekly and will be visited every two weeks to check lesions. standardization (Determine the amount of Dry Extract Powder) was performed based on Epigallocatechin. Formulation of topical preparation of green tea extract based on oil cream in water containing 19% Sinecatechin (7% Epigallocatechin). The components of the cream include dry extract of green tea, distilled water, glycerin, tween 89, cetyl alcohol, liquid paraffin and oeserin. Finally, a 10% cream containing green tea extract was prepared in 15 g tubes. The cream is used three times a day for 12 weeks or until complete clearance.

Category

Treatment - Drugs

2

Description

In Control group Pedophilin solution 10% is used once a week by the researcher for the patient up to 6 weeks or until complete clearance. In this study, pedophilein solution was prepared by the pharmacist's advisor at the Faculty of Medicine's Laboratory and administered as 10% solution once a week by The researcher will be used for the patient until complete clearance. To prevent damage to the healthy tissue of the skin, around the lesions، vaseline cream is used. 4 to 6 hours after application, the skin should be washed

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hakim Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Mashhad 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
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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