

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical study of safety and efficacy of DMA110 topical gel in the treatment of genital wart from Papillomavirus.

Protocol summary

Study aim

The aim of this study was to study the safety and efficacy of DMA110 topical gel in the treatment of genital wart from Papillomavirus

Design

A phase 1-2 clinical trial with controlled and parallel group, single blind, randomized in 80 patients. in order to apply the concealment in the randomization process, unique codes will be used on the drug boxes.

Settings and conduct

All patients with genital warts referred to Isfahan University of Medical Sciences clinics (Al-Zahra Hospital and ...) were assigned randomly in 2 groups, receiving DMA110 gel or Pedophilin solution 25% . Patients are visited weekly for 8 weeks and then once a month for 8 months. The size and number of the lesions and possible side effects of both treatments are recorded Carefully.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with genital warts
Exclusion criteria: Patients who need to take immune suppressive drugs such as corticosteroids , chemotherapeutic drugs or undergoing radiation therapy. Patients suffering from immune deficiency-associated diseases such as diabetes, cancer, HIV. pregnancy lactation A wound or active skin disease other than wart at the treatment site.

Intervention groups

Intervention group: DMA110 topical gel
Control group: Pedophilin solution 25%

Main outcome variables

Side effects
Size of the lesions
Number of the lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181026041466N6**

Registration date: **2021-05-25, 1400/03/04**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-25, 1400/03/04**

Update count: **0**

Registration date

2021-05-25, 1400/03/04

Registrant information

Name

Ali Aghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 8149

Email address

ali.aghaei110@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-20, 1400/02/30

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical study of safety and efficacy of DMA110 topical gel in the treatment of genital wart from Papillomavirus.

Public title

Clinical study of safety and efficacy of DMA110 topical gel in the treatment of genital wart.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with genital warts

Exclusion criteria:

Patients who need to take immune suppressive drugs such as corticosteroids , chemotherapeutic drugs or undergoing radiation therapy. Patients suffering from immune deficiency-associated diseases such as diabetes, cancer, HIV. pregnancy lactation A wound or active skin disease other than wart at the treatment site

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization with quadruple blocks. blocks are produced by use of the online site (www.sealedenvelope.com).

Blinding (investigator's opinion)

Single blinded

Blinding description

Data analyzer will not be aware of the assigned groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Road

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2021-04-10, 1400/01/21

Ethics committee reference number

IR.AJUMS.REC.1400.016

Health conditions studied

1

Description of health condition studied

Genital wart

ICD-10 code

A63.0

ICD-10 code description

Anogenital (venereal) warts

Primary outcomes

1

Description

side effects from treatment

Timepoint

In 7, 14, 21, 28, 35, 42, 49, 56, 84, 112, 140, 168, 196 and 238 days.

Method of measurement

Inspection and clinical examination, Patients' complaints.

2

Description

measurement of genital wart size

Timepoint

In 0, 7, 14, 21, 28, 35, 42, 49, 56, 84, 112, 140, 168, 196 and 238 days.

Method of measurement

caliper

3

Description

Number of warts

Timepoint

In 0, 7, 14, 21, 28, 35, 42, 49, 56, 84, 112, 140, 168, 196 and 238 days.

Method of measurement

Clinical counting

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: DMA110 Herbal topical gel made by Ryka pharmaceutical co containing Green tea and garlic extract. taking 2-3 times a day on all warts until Complete removal of lesions and Maximum 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: In Control group Pedophilin solution 25% is used once a week by the researcher for the patient up to 6 weeks or 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

Sedighe tahere Hospital

Full name of responsible person

Fariba Iraj

Street address

Khorram street

City

Isfahan

Province

Isfahan

Postal code

814651148

Phone

+98 31 3335 9090

Email

Derm@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rayka raya teb co

Full name of responsible person

ali aghaei

Street address

Arak street, Nejatollahi Ave.

City

Tehran

Province

Tehran

Postal code

1598945113

Phone

+98 21 8894 1935

Email

Rykapharmaceuticalco@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rayka raya teb co

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Alireza Malayeri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Pharmacy school, Golestan.

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malayeri.a@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Alireza Malayeri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Alireza Malayeri

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

Only a part of data will be shared.

When the data will become available and for how long

The access period will be 6 months after the publication of the results.

To whom data/document is available

The information obtained will only be available to researchers working in universities and science centers.

Under which criteria data/document could be used

Six months after the publication of this study papers, the obtained data will be available to the applicant researchers for further analysis.

From where data/document is obtainable

Applicants can be contacted with corresponding author by e-mail.

What processes are involved for a request to access data/document

Applicants will be able to access the obtained data from the current study by sending an email to the corresponding author up to one month.

Comments