Comparison of the therapeutic effects of Euphorbia Helioscopia latex with cryotherapy on common and plantar warts

Protocol summary

**Study aim**
Comparison of the therapeutic Effect of euphorbia helioscopia latex with Cryotherapy in treatment of common and plantar warts

**Design**
We choose 100 patient with bilateral common and plantar warts and use cryotherapy for one side warts and use euphorbia helioscopia latex for the other side.

**Settings and conduct**
Place of study: Dermatology Clinic of Imam Khomeini Hospital in Ardebil 100 patients will be selected with bilateral warts. After obtaining informed consent from the patient and recording personal information, the size of the warts will be recorded with anatomical location and photos of the lesions. Then, for warts on the one side, cryotherapy and for the opposite side warts will be used topically the latex of euphorbia helioscopia. The treatment sessions will be repeated q 2 weeks and will be repeated for 3 times. Each time the size of the warts is recorded.

**Participants/inclusion and exclusion criteria**
Participants include 5-40 y. old people. They have negative PMH. They have the right to participate in the study. They can be involved; Conditions of non entering and leaving the study include pregnancy, incontinence of uncontrolled side effects, dissatisfaction, failure to continue cooperation and ...

**Intervention groups**
The study includ, cryotherapy and topical use of the euphorbia helioscopia latex on common and plantar warts.

**Main outcome variables**
Determine the therapeutic Effect of euphorbia helioscopia latex on common and plantar warts; Determine the therapeutic efficacy of euphorbia helioscopia latex versus cryotherapy on common and plantar warts; Determination of Side effect of the latex on common and plantar warts; Removing warts; Reducing in pain of therapy.

General information

**Reason for update**
Acronym
**IRCT registration information**
IRCT registration number: IRCT20180807040734N1
Registration date: 2018-10-14, 1397/07/22
Registration timing: registered_while_recruiting

Last update: 2018-10-14, 1397/07/22
Update count: 0
**Registration date**
2018-10-14, 1397/07/22
**Registrant information**
Name
Ava Bohlouli
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 45 3345 2206
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ava.bohlooli@arums.ac.ir

**Recruitment status**
Recruitment complete

**Funding source**

**Expected recruitment start date**
2018-08-06, 1397/05/15
**Expected recruitment end date**
2019-02-20, 1397/12/01

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of the therapeutic effects of Euphorbia Helioscopia latex with cryotherapy on common and plantar warts

**Public title**
Comparison of the therapeutic effects of Euphorbia Helioscopia latex with cryotherapy on common and plantar warts

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
age 5-40 y. having bilateral common or plantar warts negative PMH Collaboration can be provided to the patient by the end of the project The patient has the consent to cooperate

**Exclusion criteria:**
pregnancy any systemic diseases metabolic disorders and any positive PMH uncontrollable side effects Failure to continue cooperation by the patient

**Age**
From 5 years old to 40 years old

**Gender**
Both

**Phase**
2

**Groups that have been masked**
No information

**Sample size**
Target sample size: 100

**Randomization (investigator's opinion)**
N/A

**Randomization description**
Blinding (investigator's opinion)
Not blinded

**Blinding description**
Placebo
Not used

**Assignment**
Parallel

**Other design features**

**Secondary Ids**
empty

**Ethics committees**

1

**Ethics committee**

Name of ethics committee
Ethics committee of Ardebil University of Medical Sciences

Street address
University of medical since,Daneshgah Ave,Ardebil town

City
Ardebil

Province
Ardabil

Postal code
56189-85991

**Approval date**
2017-06-19, 1396/03/29

**Ethics committee reference number**
Ir.arums.rec.1396.83

**Health conditions studied**

1

**Description of health condition studied**
common and plantar warts

**ICD-10 code**
B07

**ICD-10 code description**
Viral warts

**Primary outcomes**

1

**Description**
The amount of warts resized in response to treatment with euphorbia helioscopia latex and cryotherapy

**Timepoint**
In the first visit and after 2, 4 and 6 w.and 6 months after the last session of treatment

**Method of measurement**
With colis the largest diameter of the warts is measured and with anatomical position is recorded.

**Secondary outcomes**

1

**Description**
Pain score during the treatment

**Timepoint**
At the first session of treatment

**Method of measurement**
A score 0 to 10 will be given by the patient separately for each treatment intervention in the first session.

**Intervention groups**

1

**Description**
Intervention group 1: one side plantar and common warts.intervention In this group is the use of Euphorbia helioscopia latex. fresh and topically proportional to the size of the warts surface (0.1 ml / mm 2), which is the first session, 2 and 4 weeks later. The maximum number of treatment sessions, like cryotherapy, will be 3 sessions; Intervention group 2: common and plantar warts in the otherside, intervention in this group will use cryotherapy with the prescribed therapeutic standards. It will be done at the first session and 2, 4 weeks later.The maximum number of treatment sessions will be 3 sessions.
Treatment - Drugs

2

Description
Intervention group 2: common and plantar warts in the otherside, intervention in this group will use cryotherapy with the prescribed therapeutic standards. It will be done at the first session and 2, 4 weeks later. The maximum number of treatment sessions will be 3 sessions.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Khomeyni hospital
Full name of responsible person
Dr. Majid Rostami
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No.19, West 14, Enghelab Ave, Ardebil Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Dr. Ghasem Golmohammadi
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Person responsible for general inquiries

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Student
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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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
Yes - There is 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
According to the subject, patients' information is reported in terms of gender, age, size and number of germs, response to treatment, and complications without patients name...

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

To whom data/document is available
Academic and academic researchers in the pharmaceutical industry

Under which criteria data/document could be used
Upon confirmation from the university, information will be provided to the applicant for further medication or further study.

From where data/document is obtainable
With the research unit of Ardabil University of medical sciences, Agree with Dr. Majid Rostami or me.09141599447

What processes are involved for a request to access data/document
Referring to Ardabil Medical School ... which will provide the necessary guidance

Comments