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Prevention of recurrence of genital wart lesions after laser and cryotherapy using green tea extract

Submission date
12/03/2018

Recruitment status
No longer recruiting

Registration date
22/03/2018

Overall study status
Completed

Last Edited
19/05/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
External genital warts (EGW) are the most common viral sexually transmitted infection. Ablative treatments like cryotherapy, curettage and CO2 laser therapy offer rapid onset of effect, fast clearance, and reduction of viral load. However, these procedures are associated with high recurrence rates (RR) of 20–77% in the short and medium term and do not provide sustained clearance. After laser therapy removal of EGW, a RR up to 60% has been reported. Topical sinecatechins 10% is a patient-applied regimen for the treatment of EGW with a low RR (6.5%) at 3 months after completion of the therapy in the pivotal trials conducted so far. Sinecatechins can be considered a suitable proactive sequential therapy (PST) after ablative strategies to obtain a low RR. No prospective data are available so far regarding the efficacy of sinecatechins 10% as PST. We evaluated, the efficacy and tolerability of topical sinecatechins 10% applied twice daily in subjects with recurrent EGW after ablative therapies with CO2 laser or cryotherapy in a multicenter randomised masked outcome trial trial.

Who can participate?
Adults with multiple external genital warts.

What does the study involve?
The treatment is an ointment containing sinecatechins extracted from green tea. The ointment is applied twice a day to areas where genital warts have been removed using laser or cryotherapy.

What are the possible benefits and risks of participating?
The ointment of green tea extract evaluated in this trial can be considered safe because no systemic side effects have been recorded in clinical trials performed in more than 1500 subjects so far. Self-limited, (in general mild or moderate), local reactions like burning and itching sensations might be observed in up to 60% of the subjects but these side effects disappear in few days. The potential benefit is the preventive effect in lowering recurrence percentage of new genital warts lesions, therefore reducing the need for, and associated risk, time loss and cost of, additional ablative procedures (laser, cryotherapy etc).

Where is the study run from?
The study is run from the Dermatology Clinic, University Tor Vergata Rome. There are four centres in total.

When is the study starting and how long is it expected to run for?
The study started in June 2017 and finished in February 2018.

How long will the trial be recruiting participants for?
The trial recruited between August and October 2017.

Who is the main contact?
Dr Massimo Milani
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
VEREGEN1/17

Study information

Scientific Title
Efficacy of sinecatechins 10% as proactive sequential therapy of external and perianal genital warts after ablative therapy: A prospective randomized multicenter study

Study objectives

To assess if the use of topical sinecatechins 10% (green tea extract) as sequential proactive treatment after ablative therapies (laser cryotherapy) could reduce the risk of recurrence of new genital wart lesions

Ethics approval required
Old ethics approval format

Ethics approval(s)
IRB of Tor Vergata University, 12/07/2017, RS 116/17

Study design
Prospective controlled randomized parallel group (3:1) masked-outcome assessment multicenter trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
External genital warts

Interventions
Veregen (ointment formulation of 10% sinecatechins derived from green tea extract) was applied in the area of condyloma previously treated with laser or cryotherapy. Patients were instructed to apply the ointment twice daily, at 12-h intervals, for 3 months. Control group patients received no treatment after ablation.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Veregen (topical 10% sinecatechins: green tea extract)

Primary outcome measure
Recurrence of new external genital warts at 3 months after the last ablative treatment session

Secondary outcome measures
1. Tolerability
2. Safety profile
At each study visit at months 1, 2 and 3, the investigator assessed local skin signs, including erythema, oedema, induration, vesicles, erosion/ulceration, other skin signs and overall skin signs, and the patient was questioned about local skin symptoms, including burning, itching, pain, other skin symptoms and overall skin symptoms. Intensity of all skin reactions at the site of application was graded as: none, mild (local skin reaction which can be easily tolerated), moderate (local skin reaction which is associated with considerable discomfort, but does not prevent usual activity), or severe (local skin reaction which substantially interferes with the patient's usual activity).

Overall study start date
01/06/2017

Completion date
28/02/2018

Eligibility

Key inclusion criteria
Presence of multiple external genital warts eligible for ablative treatments

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80 (with a 3:1 balanced design)

Key exclusion criteria
1. HIV-positive subjects
2. Acute inflammatory skin disease

Date of first enrolment
01/08/2017

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
Italy

Study participating centre
Dermatology Clinic University Tor Vergata Rome
Viale Oxford, 81 - 00133 Roma
Rome
Italy
00133

Study participating centre
Dermatology Clinic University of Catania
Catania
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100200

Sponsor information

Organisation
Cantabria Labs Difa Cooper

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Sponsor type
Industry

ROR
https://ror.org/044sr7e96

Funder(s)

Funder type
Not defined

Funder Name
Difa Cooper

Results and Publications

Publication and dissemination plan
The plan is to submit the manuscript to an international peer-review journal

Intention to publish date
01/06/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019		Yes	No
Results article	Follow up	01/02/2022	19/05/2023	Yes	No