Pharmacokinetic analysis of sinecathechins ointment 10% (Veregen) by means of Raman micro-spectroscopy in the skin of healthy volunteers

Published: 16-08-2016
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To gain insight in the pharmacokinetics of sinecathechins ointment 10% (Veregen) applied on healthy skin, using Raman micro-spectroscopy and chromatography of tape strips.

Ethical review	Approved WMO
Status	Completed
Health condition type	Viral infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON42887

Source
ToetsingOnline

Brief title
FARAO-study

Condition

- Viral infectious disorders
- Cutaneous neoplasms benign

Synonym
Condyloma accuminata, genital warts

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Medigene

Intervention

Keyword: pharmacokinetics, sinecathechins, skin

Outcome measures

Primary outcome

The levels of sinecathechins in the stratum corneum of the skin over time as

measured by Raman micro-spectroscopy.

Secondary outcome

The levels of sinecathechins in the stratum corneum of the skin over time as

measured by chromatography of tape strips.

Study description

Background summary

Sinecathechins ointment 10% (Veregen, formerly called Polyphenon E) is a registered local therapy for genital warts. In the studies conducted for registration, the ointment was applied 3 times a day (1). Apart from the idea that there would be a continuous local presence of sinecathechins throughout the day, a true rationale for this frequency of application was never provided.

Earlier pharmacokinetic studies for sinecathechins, an ingredient of green tea, compared local application with sinecathechins ointment and the ingestion of green tea. The levels of sinecathechins were measured in blood samples. These studies showed that sinecathechins applied on skin do not lead to detectable amounts of sinecathechins in blood, thus making pharmacokinetic analysis and finding a rationale for frequency of application challenging (2).

The reason for the current study is to explore the pharmacokinetics of locally applied sinecathechins in the skin.

When therapeutic ointments are applied on intact skin, the stratum corneum (top layer of the skin) functions as a reservoir for the active ingredient of this ointment. The active ingredient can then gradually be taken up into deeper layers of the skin (epidermal and dermal layers respectively) (3). When

sufficient amounts of an active ingredient already are present in the stratum corneum after one application a day, multiple applications might only increase the chance of side effects without improving efficacy.

Minimizing the necessary frequency of application of topically applied therapeutics is aimed at reducing cost, improving patients convenience, compliance and reducing the chance of side effects.

If the current study shows that a continuous presence of sinecathechins in the stratum corneum might be achieved with less than 3 applications a day, a dose finding study in patients with genital warts is considered.

Study objective

To gain insight in the pharmacokinetics of sinecathechins ointment 10% (Veregen) applied on healthy skin, using Raman micro-spectroscopy and chromatography of tape strips.

Study design

To gain insight in the pharmacokinetics of sinecathechins ointment 10% (Veregen) applied on healthy skin, using chromatography of tape strips.

Study burden and risks

It is possible that the iontment used causes local and transient irritation of the skin.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria
- Age between 18 and 40 years
- Written informed consent

Exclusion criteria

Exclusion criteria
- Extensive UV exposure in the last 14 days before study and/or expected during the study.
- Active skin disease and/or traumatic skin lesions including scars and tattoos on the forearms.
- Expected use of inflammation suppressing medicines (e.g. corticosteroids, NSAIDs) during the study.
- Use of systemic suppressing drugs (e.g. prednisone, methothrexate) prior to (4 weeks) the study and/or expected use during the study.
-Severe disorders within the last 6 months before study (e.g. cancer, acute cardiac or circularity disorders, HIV, infectious hepatitis)
-pregnancy or breastfeeding
- Investigator's uncertainty about the willingness or ability of the patient to comply with the protocol requirements.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	14-11-2016
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Veregen
Generic name:	sinecathechins ointment 10%
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	16-08-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2016-000907-97-NL
CCMO	NL57691.018.16