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Treatment of Herpes zoster (shingles) with a lotion containing propolis extract

Submission date	Recruitment status	[_] Prospectively registered
15/03/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/03/2016	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/03/2016	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Herpes zoster, more commonly known as shingles, is an infection caused by the varicella-zoster virus (which also causes chicken pox). It usually affects a specific area on one side of the body, and appears in the form of a painful rash that develops into itchy blisters. Some people suffering from shingles are prescribed antiviral tablets (such as acyclovir) to take in order to speed up recovery. A previous study found that rubbing a skin lotion containing propolis onto the affected areas of the skin could help to treat shingles when used alongside antiviral therapy. Propolis is a resin-like substance from in the buds of certain trees. The aim of this study is to compare two skin creams – one that contains propolis and one that does not – in order to find out whether it is the propolis or the skin cream itself that causes an improvement in shingles patients.

Who can participate?
Adults with shingles who are able to take anti-viral therapy (acyclovir).

What does the study involve?
Participants are allocated to one of two groups in a non-random way. Those in the first group are treated with acyclovir at a dose of 200mg or 400mg per day for four weeks (depending on what dose would work best for them). These participants are also given a skin care lotion containing propolis extract to apply to the affected skin areas two to three times a day. Those in the second group are also treated with 200mg or 400mg acyclovir for four weeks. These participants also apply a skin lotion which is identical to the skin lotion used in group one except that it does not contain propolis extract. Participants in both groups are interviewed on day 3 or 4, 7, 14 and 28 of treatment in order to find out if their pain levels have been reduced since using the cream.

What are the possible benefits and risks of participating?
Participants may benefit from less pain/itching without an interference with their antiviral therapy. There are no notable risks involved with taking part in this study.

Where is the study run from?
Dr. Simona Holcová, Consultancy for Dermatology (Czech Republic)

When is the study starting and how long is it expected to run for?
February 2012 to January 2014

Who is funding the study?
Gehrlicher Pharmazeutische Extrakte GmbH (Germany)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Lotion containing propolis special extract GH 2002 0,5% vs. placebo in the treatment of Herpes zoster

Study objectives
The aim of this study was to find out whether propolis might provide an alleviation of typical Herpes zoster pain when applied on the lesions in the form of a lotion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Under the regulations of the Czech Republic approval by an ethics committee was not required due to the nature of this study as the interventional product does not interfere with the aciclovir treatment guidelines.

Study design
Single-centre placebo-controlled non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Herpes zoster

Interventions
Participants are allocated to one of two groups using sequential allocation.

Group 1: Participants are treated with acyclovir at a dose of 200 or 400 mg/day for four weeks. The participants in this group also self-apply a skin care lotion with propolis special extract 2-3 times daily on the affected skin areas.

Group 2: Participants are treated with acyclovir at a dose of 200 or 400 mg/day for four weeks. The participants in this group are also self-apply a skin care lotion with the same composition as in Group 1, except that the lotion does not contain propolis special extract. The lotion is applied 2-3 times daily on the affected skin areas.

Pain is measured using a Visual Analogue Scale (VAS) at the follow-up visits on day 3 or 4, day 7, day 14 and day 28.

Intervention Type
Other

Primary outcome measure
Pain is measured using a Visual Analogue Scale (VAS) at baseline, 3-4, 7, 14 and 28 days.

Secondary outcome measures
Development of Herpes zoster lesions is measured using physical assessments by the treating physician at baseline, 3-4, 7, 14 and 28 days.

Overall study start date
24/02/2012

Completion date
14/01/2014

Eligibility

Key inclusion criteria
1. Aged 18 to 70 years
2. Diagnosis of Herpes zoster
3. Eligible for oral treatment with acyclovir
4. No known allergy against propolis or aciclovir

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
None

Date of first enrolment
24/02/2012

Date of final enrolment
17/12/2013

Locations

Countries of recruitment
Czech Republic

Study participating centre
Dr. Simona Holcová, Consultancy for Dermatology
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Sponsor information

Organisation
Gehrlicher Pharmazeutische Extrakte GmbH

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Sponsor type
Industry

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ROR
https://ror.org/04qx49k93

Funder(s)

Funder type
Industry

Funder Name
Gehrlicher Pharmazeutische Extrakte GmbH

Results and Publications

Publication and dissemination plan
Publication of study results in a peer reviewed journal.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request