

A double-blind, placebo controlled, randomised study to assess the value of free radical scavengers in reducing inflammation induced by cryotherapy

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/03/2009	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0593115224

Study information

Scientific Title

Study objectives

The aims of the study are to investigate and quantify the response of:

1. Oedema and blister formation
2. Erythema
3. Pain induced by cryotherapy in patients receiving a combination of a high dose of systemic vitamins C and E prior to treatment in comparison to placebo group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Double-blind, placebo controlled, randomised study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Skin and Connective Tissue Diseases: Hand warts

Interventions

Double-blind, parallel group, randomised study of the effect of a high dose combined systemic vitamin C and E on inflammation-induced cryotherapy.

1. Enrolment - It is proposed to enrol 100 patients with hand warts. Each patient will be assigned a unique number. Subjects will be patients referred to the Dermatology Department for the treatment of hand warts. Subjects will be required to provide written informed consent.
2. Randomisation Treatment will be allocated by randomising patients into balanced blocks of four. The pharmaceutical company providing the drugs will be responsible for the process of randomisation.

3. Study drug administration - Patients with hyperkeratotic hand warts (size 4-8 mm) will receive either a combined preparation of vitamin C (2000 mg) and vitamin E (800 iu) daily or placebo for 7 days prior to cryotherapy to a hand wart.

4. Treatment with Cryotherapy - The wart will be treated with a single application of cryotherapy from CRY-AC spray to obtain a 1-mm halo around the wart and just sufficient to maintain this for further 10 s. The CRY-AC spray will be half full with liquid nitrogen and the nozzle will be kept approximately 1cm away from the treated lesion. Different size cardboard templates will be treated with liquid nitrogen. Patients will be seen and assessed 24 h after cryotherapy.

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Vitamin C, vitamin E

Primary outcome measure

Change in wart volume assessed 24 h after cryotherapy for the grade of oedema.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2002

Completion date

31/12/2004

Eligibility**Key inclusion criteria**

100 randomised (1:1) patients aged 18 years and over referred to the dermatology clinic for cryotherapy of hand warts that have failed to respond to topical salicylic acid preparations will be asked after appropriate counselling to participate in the trial.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2002

Date of final enrolment

31/12/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Dermatology

Warwick

United Kingdom

CV34 5BW

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type
Government

Funder Name
South Warwickshire General Hospitals NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2005		Yes	No