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

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/03/2009	Skin and Connective Tissue Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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