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Effect of penetration enhancers in topical photodynamic therapy

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	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/02/2014	Signs and Symptoms	[ ] Record updated in last year

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
N0112112993

Study information

Scientific Title
Comparison of 20% Aminolaevulinic acid (ALA) versus 20% ALA 2% dimethyl sulphoxide (DMSO) 2% ethylene diamine tetraacetic acid (EDTA) in topical photodynamic therapy

Study objectives
Do penetration enhancers increase the efficacy of photodynamic therapy (PDT)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Skin and Connective Tissue Diseases: Topical photodynamic therapy (PDT)

Interventions
Two treatment arms in the study, randomised in double blind fashion to receive either topical 20% ALA or 20% ALA, 2% EDTA cream. Both groups will then receive light treatment to the areas to which the cream has been applied. Comparison of the two groups will be by change in size of skin lesion by any tolerance of procedure.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Response of skin lesion clinically by size change at 3 month follow ups.

Secondary outcome measures
Not provided at time of registration

Overall study start date
08/04/2002

Completion date
08/04/2003

Eligibility

Key inclusion criteria
1. Patients referred for PDT as judged appropriate by dermatologists in local area
2. Patients will have basal cell carcinomas, Bowen's disease or actinic keratoses and will be randomised depending on diagnosis

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
08/04/2002

Date of final enrolment
08/04/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Epsom and St Helier NHS Trust
Carshalton
United Kingdom
SM5 1AA

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
Epsom and St Helier University 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