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Effect of penetration enhancers in topical photodynamic therapy

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/09/2003	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 04/02/2014	**Condition category** Signs and Symptoms	[_] Individual participant data [_] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Response of skin lesion clinically by size change at 3 month follow ups.

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Epsom and St Helier University Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration