

Effect of penetration enhancers in topical photodynamic therapy

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/02/2014	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ian Pearson

Contact details
Epsom and St Helier NHS Trust
Department of Dermatology
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA
+44 (0)20 8296 2000

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

Study design

Randomised controlled trial

Primary study design

Interventional

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