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

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

 Patients referred for PDT as judged appropriate by dermatologists in local area
 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