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Phase II/III study to investigate the efficacy of 5-aminolaevulinic acid (ALA)-based photodynamic therapy in the treatment of Bowen's disease, actinic keratoses and study the effect of dose fractionation for superficial basal cell carcinomas

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 07/12/2015	**Condition category** Cancer	

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
N0436118001

Study information

Scientific Title
Phase II/III study to investigate the efficacy of 5-aminolaevulinic acid (ALA)-based photodynamic therapy in the treatment of Bowen's disease, actinic keratoses and study the effect of dose fractionation for superficial basal cell carcinomas

Study objectives
To continue to investigate the efficacy of ALA-based photodynamic therapy in the treatment of Bowen's disease and actinic keratoses. To study the effect of dose fractionation for superficial basal cell carcinomas using a randomised trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised active-controlled parallel-group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bowen's disease

Interventions
Controlled trial without randomisation; Randomised controlled trial, Random allocation to:
1 Standard photodynamic therapy for superficial basal cell carcinoma
2 Dose fractionated photodynamic therapy

Intervention Type
Other

Phase
Phase II/III

Primary outcome(s)
Complete remission of skin tumour and future recurrence.

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

Completion date
01/02/2004

Eligibility

Key inclusion criteria
Recruited from clinical oncology consultants to whom patients are referred at a district general hospital. Also direct from consultant dermatologists/plastic surgeons in Leeds and Airedale.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/02/2002

Date of final enrolment
01/02/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cookridge Hospital
Leeds
United Kingdom
LS16 6QB

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration