

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	<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 07/12/2015	Condition category Cancer	<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

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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes