

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

Contact name
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Contact details
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Cookridge Hospital
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Leeds
United Kingdom
LS16 6QB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Complete remission of skin tumour and future recurrence.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/02/2002

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

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**

England

United Kingdom

Study participating centre
Cookridge Hospital
Leeds
United Kingdom
LS16 6QB

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
Hospital/treatment centre

Funder Name
Leeds Teaching 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