

A randomised controlled trial to study the side effect profile and to establish measures of efficacy using photofrin or 5-aminolaevulinic acid (ALA) photodynamic therapy in the eradication of dysplasia in Barretts columnar lined oesophagus

Submission date 26/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/08/2013	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

Version 3.1

Study information

Scientific Title

Study objectives

To determine whether photodynamic therapy for high grade dysplasia in Barrett's oesophagus using aminolaevulinic acid has less side effects than photofrin. To develop novel measures of efficacy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Berkshire Research Ethics Committee, 13/01/2006, ref: 05/Q1602/193

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

High grade dysplasia in Barrett's oesophagus

Interventions

Photodynamic therapy using 5-aminolaevulinic acid versus photofrin

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Aminolaevulinic Photofrin

Primary outcome measure

1. Eradication of high grade dysplasia
2. Prevention of oesophageal cancer
3. Side effect profiles of different types of photodynamic therapy

Secondary outcome measures

1. Quality of life outcomes
2. Develop novel methods for treatment efficacy
3. Reversal of Barrett's oesophagus

Overall study start date

01/02/2006

Completion date

01/02/2009

Eligibility

Key inclusion criteria

1. Patients with high grade dysplasia in Barrett's oesophagus but without invasive cancer
2. Aged over 21

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

66

Key exclusion criteria

1. Severe cardiovascular disease
2. Liver cirrhosis or seriously impaired hepatic or renal function
3. Depot antipsychotics
4. Concomitant chemoradiotherapy
5. Pregnancy
6. Porphyria
7. Previous photodynamic therapy

Date of first enrolment

01/02/2006

Date of final enrolment

01/02/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

National Medical Laser Centre

London

United Kingdom

W1W 7EJ

Sponsor information

Organisation

University College London (UK)

Sponsor details

Gower street

London

England

United Kingdom

WC1E 6BT

Sponsor type

University/education

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Government

Funder Name

National Medical Laser Centre (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2013		Yes	No