ISRCTN16444200 https://doi.org/10.1186/ISRCTN16444200

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	Recruitment status	[_] Prospectively registered
26/01/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/02/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/08/2013	Nutritional, Metabolic, Endocrine	

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
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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