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The use of aminolaevulinic acid (ALA) and photodynamic therapy (PDT) in the treatment of Barrett's oesophagus

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 12/12/2013	**Condition category** Digestive System	

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

940129

Study information

Scientific Title

Study objectives
Barrett's oesophagus is an acquired condition due to long-standing acid reflux which destroys the normal oesophageal lining. This is replaced by a lining which carries a significant risk of malignant change. Current therapeutic approaches aim to reduce oesophageal exposure to refluxing stomach contents either by medical or surgical means, but this may not prevent the development of cancer. Alternate forms of therapy are therefore required. PDT is a new form of cancer treatment in which cell damage is achieved by the action of laser light of specific wavelength upon a light sensitive drug which is taken up by malignant or pre-malignant tissue. This results in targeting of the treatment to the tumour and limits normal tissue damage. The clinical use of PDT has been restricted by the side effects of the light sensitive drugs. A new agent, ALA with few side effects has been successfully used in the treatment of skin and bladder cancer. The aim of the study is to evaluate the use of PDT using ALA and green light delivered from a copper vapour laser in the treatment of Barrett's oesophagus. The researchers also aim to quantify and characterise tissue porphyrin levels from biopsy samples, which has not previously been done in this condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Barrett's oesophagus

Interventions

Patients will be randomised either to a treatment group (receiving treatment as above) or a control group (where the treatment will be identical except that no ALA will be added to the carrier medium). The clinician and the patient will be blinded to the group to which individuals are allocated. As gastric acid suppression with omeprazole has been shown to have a partial effect in reversing Barrett's oesophagus and reduced exposure to acid may encourage re-epithelialisation with normal squamous mucosa, all patients will receive omeprazole.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Aminolaevulinic acid

Primary outcome measure
Ablation of low grade dysplastic epithelium

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/1995

Completion date
31/03/1996

Eligibility

Key inclusion criteria
Patients with biopsy proven high grade dysplasia associated with Barrett's oesophagus who would otherwise require oesophagogastrectomy will be offered ALA-induced PDT. Two groups:
1. Patients with high grade dysplasia who will receive PDT followed by surgery if there is no response
2. Patients with low grade dysplasia who are at lower risk of carcinoma will be entered into a controlled trial and followed up by endoscopy to assess the efficacy and duration of any treatment effects.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/04/1995

Date of final enrolment
31/03/1996

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Surgery and Anaesthetics
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Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

Funder Name
NHS Executive Trent

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	01/11/2000		Yes	No