

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

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<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/12/2013	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## 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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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# 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

Sheffield

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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**

<http://www.doh.gov.uk>

# 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?
<a href="#">Results article</a>	results	01/11/2000		Yes	No