Endoscopic ablation of Barrett's oesophagus: a randomised controlled trial comparing photodynamic therapy (PDT) versus argon beam plasma coagulation (ABPC)

Submission date 12/09/2003	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 12/09/2003	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 13/07/2009	Condition category Digestive System	[_] 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

N0059089106

Study information

Scientific Title

Study objectives

To compare argon beam plasma coagulation (ABPC) and photodynamic therapy (PDT) in the ablation of metaplastic and low grade dysplastic Barrett's oesophagus, in a randomised controlled prospective clinical trial.

Ethics approval required Old ethics approval format

Ethics approval(s) South Sheffield research ethics committee (REC) approval received (ref: 00/031)

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 Compare ABPC and PDT in the ablation of metaplastic and low grade dysplastic Barrett's oesophagus.

Intervention Type Other

Phase Not Applicable

Primary outcome measure Tolerability of treatment

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2000

Completion date 01/11/2004

Eligibility

Key inclusion criteria

- 1. Currently in an endoscopic screening programme
- 2. Aged 18 years or older, either sex
- 3. Biopsy proven Barretts epithelium with a median length of 4 cm

Participant type(s) Patient

Age group Adult

Lower age limit 18 Years

Sex Both

Target number of participants 56

Key exclusion criteria Does not meet inclusion criteria

Date of first enrolment 01/04/2000

Date of final enrolment 01/11/2004

Locations

Countries of recruitment England

United Kingdom

Study participating centre

University of Sheffield Sheffield United Kingdom S10 2JF

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 Government

Funder Name Sheffield Teaching Hospitals NHS Foundation Trust (UK) - Central Campus

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?
<u>Results article</u>	results	01/12/2004		Yes	No