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A national patient registry for radiofrequency ablation (RFA) for Barrett's oesophagus

Submission date 12/06/2013	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol
Registration date 14/06/2013	**Overall study status** Ongoing	[_] Statistical analysis plan [X] Results
Last Edited 08/02/2021	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-new-treatment-2-pre-cancerous-conditions-affecting-food-pipe-halo

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol Version 3.1

Study information

Scientific Title
Radiofrequency ablation of Barrett's columnar lined oesophagus and squamous dysplasia: multicentre trial with long term follow up using a central database

Study objectives
The aim of this prospective, multi-centre patient registry study is to provide a tool for participating physician investigators to collect outcome data related to the use of the HALO Ablation Systems. We hypothesise that RFA is safe and effective in treating patients with dysplasia arising in Barrett's oesophagus and will maintain a durable response.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service (NRES), ref: 08/H0714/27

Study design
Prospective multi-centre patient registry

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Oesophageal Cancer/ Barrett's Oesophagus

Interventions
HALO radiofrequency ablation (HALO RFA)
The study collects the outcomes of patients undergoing the intervention which is RFA. The study collects not just demographic data on patients eligible for RFA treatment but also the effectiveness of the treatment in curing them of early oesophageal neoplasia. The study collates the number of procedures required to get to this point but also examines the reasons why we fail in a minority of patients so we can try understand these patients to help improve our practice and streamline our approach to them.

Intervention Type

Procedure/Surgery

Primary outcome measure
1. Endoscopic clearance rate for Barrett's esophagus. Percentage of patients with no endoscopically visible Barrett's oesophagus at 1 year follow-up
2. Histological clearance rate for intestinal metaplasia. Percentage of patients with no histological evidence of intestinal metaplasia at 1 year follow-up
3. Histological clearance rate for columnar dysplasia. Percentage of patients with baseline dysplasia who have no histological evidence of dysplasia at 1 year follow-up
4. Sub-squamous intestinal metaplasia. Percentage of patients at 1 year follow-up with sub-squamous intestinal metaplasia, with or without dysplasia, that is covered completely by an intact layer of squamous epithelium with no communication with the surface

Secondary outcome measures
Ability of aneuploidy and other molecular changes to predict success or failure of this therapy.

Overall study start date
31/03/2008

Completion date
31/03/2028

Eligibility

Key inclusion criteria
1. Patients will be recruited from those referred for ablative management of Barrett's oesopahgus or squamous dysplasia with HALO RFA
2. Patients must have no contraindications to endoscopy
3. Males and non-pregnant females over the age of 21 years. Female patients who are pre-menopausal must practice a medically acceptable form of contraception.
4. Patients must sign an informed consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
21 Years

Sex
Both

Target number of participants
1000

Key exclusion criteria
1. Presence of invasive carcinoma of the oesophagus
2. Patients in whom endoscopy is contraindicated

3. Patients with oesophageal varices
4. Previous radiotherapy
5. Patients who have undergone Hellers myotomy
6. Pregnant females
7. People under the age of 21 years

Date of first enrolment
31/03/2008

Date of final enrolment
30/09/2027

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London Hospitals NHS Trust
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
Joint UCLH/UCL Biomedical Research Unit (UK)

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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
BAARX Medical Inc. (USA)

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	01/08/2015		Yes	No
Results article	results	05/02/2021	08/02/2021	Yes	No