

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

<b>Submission date</b> 12/06/2013	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/06/2013	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/02/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> 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 oesophagus 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)

**Sponsor details**

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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?
<a href="#">Results article</a>	results	01/08/2015		Yes	No
<a href="#">Results article</a>	results	05/02/2021	08/02/2021	Yes	No