

Prevalence of metabolic obesity in patients with Barrett's Oesophagus and its potential role in carcinogenesis

Submission date 12/07/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/01/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/06/2016	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-obesity-people-barretts-oesophagus>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Prevalence of metabolic obesity in patients with Barrett's Oesophagus and its potential role in carcinogenesis: a single centre non-randomised controlled trial

Study objectives

The aim of this study is to investigate whether there is a connection between obesity and the development of Barrett's Oesophagus.

Ethics approval required

Old ethics approval format

Ethics approval(s)

East Central London Research Ethics Committee, 09/02/2011, ref: 10/H0721/83

Study design

Single centre non-randomised controlled trial

Primary study design

Observational

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Barrett's Oesophagus and metabolic obesity

Interventions

The study will be divided in 2 phases (total duration 12 months):

Phase 1: Recruitment, collection of data, endoscopy (OGD) biopsy and histology, blood tests (duration 8 months).

1. Subjects with known Barretts Oesophagus will be recruited from patients booked to have an OGD on a list dedicated to a Barretts oesophagus surveillance programme undertaken at University College Hospital, UK.
2. The control group will be recruited from patients booked to have an elective OGD for other gastrointestinal indications (negative at endoscopy for Barretts Oesophagus).

Phase 2: Data collection and analysis (duration 4 months)

1. Data will be entered into a database
2. Data analysis

The prevalence of obesity, overweight and metabolic obesity will be determined. Anthropometric measurements and body composition (bioimpedance) and biochemical indices of metabolic syndrome will be measured. In those subjects with Barrett's Oesophagus histological presence of metaplasia/dysplasia will also be assessed.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Prevalence of overweight, obesity, and metabolic obesity in subjects with Barrett's Oesophagus as compared to subjects without Barrett's Oesophagus (standardised for age and sex).

All the measures will be done only once at baseline, when patients attend their endoscopy test as part of their clinical management.

No follow-up is required.

Secondary outcome measures

1. The characteristics of body composition, metabolic parameters and serum level of adiponectin /leptin in obese, overweight and metabolic obese subjects compared to those of normal weight.
2. The prevalence of abdominal obesity (in obese and overweight subjects) and metabolic obesity in subjects with dysplastic Barrett's oesophagus compared to those without dysplasia.

All the measures will be done only once at baseline, when patients attend their endoscopy test as part of their clinical management. No follow-up is required.

Overall study start date

01/05/2011

Completion date

30/05/2013

Eligibility

Key inclusion criteria

1. Able to understand the nature and requirements of the study and to provide written informed consent
2. Aged 18 - 79 years
3. Booked to undergo routine oesophagogastrroduodenoscopy

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

A total of 460 subjects will be recruited: 230 with known Barrett's Oesophagus and 230 without Barrett's Oesophagus

Key exclusion criteria

1. Weight loss of more than 10% in the last year
2. Known decompensated liver disease
3. Coeliac disease
4. Inflammatory bowel disease
5. Previous upper gastrointestinal tract surgery
6. Known malignancy or undergoing treatment for previously resected malignancy
7. Inability to provide informed consent

Date of first enrolment

01/05/2011

Date of final enrolment

30/04/2012

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

University College London Hospital

London

United Kingdom

NW1 2BU

Sponsor information**Organisation**

University College London Hospital [UCLH] (UK)

Sponsor details

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Sponsor type

University/education

Website

<http://www.uclh.org/>

ROR

<https://ror.org/02jx3x895>

Funder(s)**Funder type**

Charity

Funder Name

University College London Hospital (UCLH) Charities - Clinical Research and Development Committee (CRDC) (UK) ref: GCT/2011/MB-Po

Results and Publications**Publication and dissemination plan**

Planned publication in a peer reviewed journal.

Intention to publish date

01/03/2016

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016		Yes	No