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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/01/2012	**Overall study status** Completed	
Last Edited 06/06/2016	**Condition category** Digestive System	

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

v.2 06/01/2011

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: Gata 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 oesophagogastroduodenoscopy

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)

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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