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Benefits of weight loss in obese patients with asthma: mechanical or immunological mechanisms?

Submission date 12/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/12/2005	**Overall study status** Completed	
Last Edited 21/03/2012	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
04/048

Study information

Scientific Title

Study objectives
Epidemiological studies suggest higher prevalence in obese subjects. Weight loss improves many features of asthma. Whilst lung function will improve with weight loss as a result of mechanical work, it is difficult to explain improvements in bronchial hyper-reactivity and airway inflammation purely on a mechanical basis. Obesity is associated with a state of immune activation that could amplify the process of autoimmunity.

We hypothesize that immunological mechanisms partly account for the relationship between obesity and asthma. More specifically, we propose that increased concentrations of the adipokines leptin and tumour necrosis factor alpha and reduced concentrations of adiponectin in obese subjects are promoters of inflammation in asthma, and that improvements in asthma with weight loss are related to changes in the systemic and local (within the bronchial tree) concentrations of these factors as well as a reduction in mechanical work.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Asthma and obesity

Interventions
Dietary intervention: Meal replacement therapy for six months plus dietition advice and support for intervention group versus healthy eating leaflet for control group

Exhaled nitric oxide measurements.
Methacholine challenge testing - tidal breathing method.
Airway resistance with plethysmography.
Induced sputum plus sputum cell counts and supernatent inflammatory markers.
Blood inflammatory markers.
Height, weight and bioimpedence.
SGRQ, SF36, IQWOL-LITE questionnaires.
Peak flow and symptom diary monitoring.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Expected weight loss in the intensive group of 10 to 12 kg (10 - 20% body weight), compared to minimal weight loss in the conventional group. This should result in significant improvements in pulmonary function i.e. reduced bronchoconstriction, reduced peak flow variability and reduced bronchial hyper-reactivity.

Secondary outcome measures
1. Reduction in systemic inflammation in the intensively treated group
2. Reduction in markers of local airway inflammation in the intensively treated group
3. Improvement in health status of intensively treated group

Overall study start date
01/01/2005

Completion date
01/01/2007

Eligibility

Key inclusion criteria
1. Obesity (body mass index more than 30 kg/m^2
2. Age 18 to 65 years
3. Asthma requiring treatment with at least a long-acting inhaled corticosteroid and an inhaled beta agonist

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Subjects on long-term oral corticosteroids
2. Diabetes mellitus
3. Pregnancy or breastfeeding
4. History of major eating disorder
5. History of food allergy to any component of Slimfast
6. Major psychiatric disease
7. Current smokers
8. Uncontrolled thyroid disease
9. History of severe cardiac, hepatic or renal disease, malignancy, or any other condition that might, in the opinion of the investigators preclude completion of the study

Date of first enrolment
01/01/2005

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Sciences Centre
Liverpool
United Kingdom
L9 7AL

Sponsor information

Organisation
University of Liverpool (UK)

Sponsor details
Liverpool
England

United Kingdom
L69 3BX

Sponsor type
University/education

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Charity

Funder Name
Asthma UK (Project ID 04/048).

Alternative Name(s)
Asthma UK, Asthma + Lung UK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	01/03/2012		Yes	No