

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
Registration date 02/12/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/03/2012	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Asthma and obesity

Interventions

Dietary intervention: Meal replacement therapy for six months plus dietitian 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 supernatant inflammatory markers.

Blood inflammatory markers.

Height, weight and bioimpedance.

SGRQ, SF36, IQWOL-LITE questionnaires.

Peak flow and symptom diary monitoring.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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.

Key secondary outcome(s)

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

Completion date

01/01/2007

Eligibility**Key inclusion criteria**

1. Obesity (body mass index more than 30 kg/m²)
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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre

Clinical Sciences Centre

Liverpool

United Kingdom

L9 7AL

Sponsor information

Organisation

University of Liverpool (UK)

ROR

<https://ror.org/04xs57h96>

Funder(s)

Funder type

Charity

Funder Name

Asthma UK (Project ID 04/048).

Alternative Name(s)

asthmalunguk, Asthma + Lung UK, Asthma UK

Funding Body Type

Private sector organisation

Funding Body Subtype

Research institutes and centers

Location

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2012		Yes	No