Options

Print

PDF

Set alert

Fast track

PubMed record

Original research

Share

|

You need to be logged in to see your keywords

Systematic review of the clinical efficacy of sibutramine and orlistat in weight loss, quality of life and its adverse effects in obese adolescents

Garcia Diaz E, Martin Folgueras T

CRD summary
The review concluded that sibutramine and orlistat in combination with a hypocaloric diet and changes in lifestyle in obese adolescents achieve a short-term loss of weight greater than that achieved through the dietary-behavioural therapy alone. The review had methodological and data limitations that limit the reliability of the authors conclusions.

Authors' objectives
To determine the effect of sibutramine and orlistat in terms of weight loss, quality of life and adverse effects in obese adolescents.

Searching
MEDLINE, TRIP and The Cochrane Library were searched for articles published in English in the last 10 years. Search terms were reported. Reference lists of retrieved articles were searched.

Study selection
Randomised controlled trials (RCTs) of sibutramine or orlistat plus dietary treatment versus placebo plus dietary treatment in obese participants aged between 12 and 18 years were eligible for inclusion. Obesity had to be diagnosed by a body mass index (BMI) of between 30 and 44kg/m². Trials had to use the absolute change in initial BMI or the percentage change in initial BMI as the primary outcome measure.

The included trials studied sibutramine (10 to 15mg/day) or orlistat (120mg three times a day) alone or in combination with diet. Controls were diet plus placebo or placebo alone. Some trials excluded smokers and patients with diabetes or hypertension. Study duration was six to 12 months.

The authors did not state how many reviewers performed study selection.

Assessment of study quality
Study validity was assessed using the Jadad scale of blinding, allocation concealment, randomisation and drop-outs to give a maximum score out of five.

The authors did not state how many reviewers performed validity assessment.

Data extraction
Data were extracted on an intention-to-treat basis on weight loss, quality of life and adverse events.

The authors did not state how many reviewers performed data extraction.

Methods of synthesis
A narrative synthesis was presented. Studies were grouped by drug.

Results of the review
Nine trials (1,829 participants, range 24 to 539) were included in the review: six trials of sibutramine and three trials of orlistat. The quality of the included studies was variable: four trials scored 5, two trials scored 4, two trials scored 3 and one scored 2.

Weight loss: Three out of four sibutramine trials showed a statistically significantly greater reduction in BMI compared with placebo. Two out of three trials of orlistat showed a statistically significantly greater reduction in BMI compared with placebo. Change in BMI for sibutramine ranged from -1.5 to -3.6kg/m². Change in BMI for orlistat ranged from -0.55 to -4.09 kg/m². Three out of five sibutramine trials showed a statistically significantly greater absolute initial weight change compared with placebo. Two out of two trials of orlistat showed a statistically significantly greater absolute initial weight change compared with placebo after 12 months. Change in initial weight for sibutramine ranged from -2.81 to -10.3kg/m², and change in initial weight for orlistat ranged from +0.53 to -6.27kg/m².

Quality of life: One trial indicated that there was no significant difference between placebo and sibutramine groups; both patient groups showed improvements in quality of life at the end of the study.

Adverse events: Two trials reported similar adverse events between sibutramine and placebo apart from tachycardia, which was higher with sibutramine (13%) compared with placebo (6%). Other side-effects associated with sibutramine were dry mouth, constipation, dizziness, insomnia and hypertension, all with a frequency of less than 12%. The most common adverse effects associated with orlistat were gastrointestinal, mostly mild to moderate.

Authors' conclusions
Sibutramine and orlistat in combination with a hypocaloric diet and changes in lifestyle in obese adolescents achieved a short-term loss of weight greater than that achieved through dietary-behavioural therapy alone.

CRD commentary
Inclusion criteria for the review were broadly defined. Three relevant data sources were searched. There was potential for language bias, as only articles in English were included. The authors stated some potential for publication bias as they did not contact authors for unpublished data. The inclusion criteria appeared to limit studies to those that assessed interventions and controls in combination with dietary treatment, although some of the included studies did not appear to meet this criterion. The authors did not state whether they attempted to reduce reviewer error and bias during the review process.

Quality assessment indicated that the quality of the included studies was variable. Some of the trials had small sample sizes, high drop-out rates and were only short-term. The authors stated that some of the outcome measures did not take account of factors such as growth in children. Studies were narratively synthesised. The authors reported that heterogeneity across studies precluded meta-analysis but did not report the details.

The review had methodological and data limitations that limit the reliability of the authors' conclusions.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice. The authors stated that the Spanish Agency for Medicines and Health Products had suspended the marketing of Sibutramine in 2010 due to cardiovascular risk.

Research: The authors stated that further studies were needed to confirm the long-term safety of orlistat (typically associated with mild-moderate gastrointestinal adverse effects). The limited evidence about the impact on quality of life of these drugs meant that further research was needed.

Funding
Not stated.

Bibliographic details
Garcia Diaz E, Martin Folgueras T. Systematic review of the clinical efficacy of sibutramine and orlistat in weight loss, quality of life and its adverse effects in obese adolescents. Nutricion Hospitalaria 2011; 26(3): 451-457

PubMedID
21892560

Original Paper URL
http://onlinelibrary.wiley.com/doi/10.1111/j.1471-0528.2011.03065.x/abstract

Indexing Status
Subject indexing assigned by NLM

MeSH
Adolescent; Anti-Obesity Agents /adverse effects /therapeutic use; Appetite Depressants /adverse effects /therapeutic use; Cyclobutanes /adverse effects /therapeutic use; Diet; Female; Humans; Lactones /adverse effects /therapeutic use; Male; Obesity /diet therapy /drug therapy /psychology; Quality of Life; Randomized Controlled Trials as Topic; Weight Loss /drug effects

AccessionNumber
12012001182

Database entry date
08/08/2012

Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.

Database of Abstracts of Reviews of Effects (DARE)
Produced by the Centre for Reviews and Dissemination
Copyright © 2012 University of York