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The influence of Orlistat (Xenical®) on weight loss in overweight and obese adults: a systematic review

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Obesity is a growing problem throughout the world, which is projected to cause major health problems and become an increasing burden on health services in Scotland[1]. In 2001, the cost of treating obesity and obesity-related diseases in Scotland was estimated at £171 million[2]. One approach to treatment is to inhibit the absorption of dietary fat by blocking the action of gastrointestinal lipases. Orlistat (Xenical®) was licensed in 1999 for treatment of obesity in adults, with a dose of 120 mg three times daily. From April 2009 a lower dose of 60 mg three times daily was licensed for sale over the counter to adults with a BMI of 28 or greater, under the trade name Alli®. We set out to systematically review and critically appraise studies that investigated the use of Orlistat 120 mg three times daily as a weight control drug, in order to determine its clinical effectiveness.

A search was carried out in Ovid MEDLINE (R) from 1950 to January Week 1, 2011. The search strategy included randomised, double-blind, placebo-controlled trials using Orlistat in adults with no significant other disease, in which weight change was a reported outcome. Five trials were found, which satisfied the search criteria. The strategy was adapted for use in EMBASE but no additional trials were found. Searching of the International Journal of Obesity identified one further trial. The six included trials ranged in duration from 1 to 2 years, with a total 3386 people were randomised of whom 2205 (65.1 %) completed. The mean age of the participants was 42.9 years and the mean BMI was 36.1 kg/m^2 with 84.1 % of the participants being women. All participants received advice about a low energy diet (2092–2510.4 kJ/d energy deficit; 500–600 kcal/d energy deficit) and behavioural counselling. All studies were funded by the manufacturer of Xenical®, Hoffman LaRoche.

The mean weight loss in the groups on Orlistat 120 mg three times a day ranged from 6.5 to 10.2 % of initial body weight, compared with 3.0–6.6 % in the placebo groups. The percentage of participants who lost over 5 % of their initial body weight was 29.7–65.7 % of the participants in the Orlistat groups and 21.0–43.6 % of the participants in the placebo groups. Gastro-intestinal side effects such as fatty/oily stool, flatus and abdominal pain were common but were mostly classed as mild or moderate rather than severe. Critical appraisal of the studies using a modified version of the CASP checklist[3] found that all studies scored well except on details of the allocation method and information on power calculations, which were missing in three out of the six studies for both items.

The results suggest that Orlistat 120 mg three times a day increases weight loss in overweight and obese adults by about 4 % of initial body weight, i.e. about 4 kg in a 100 kg adult, and increases the proportion of people who lose 5 % or more of their body weight while on an energy deficit diet. The effectiveness of the lower dose of 60 mg three times a day in Alli® remains to be established.

1. The Scottish Public Health Observatory (2007) Obesity in Scotland: An Epidemiological Briefing.
2. Walker A (2003) The Cost of Doing Nothing – the economics of obesity in Scotland. National Obesity Forum.
3. Public Health Resource Unit, England. Critical Appraisal Skills Programme (CASP) 2006.