

Colesevelam for type 2 diabetes mellitus (Protocol).

ABSTRACT

Colesevelam was originally approved for the treatment of hyperlipidaemia (high blood lipids) in the 2000s but has been shown to improve blood sugar as well. Therefore, we investigated its role in the management of type 2 diabetes mellitus. A total of 1450 patients took part in six studies investigating colesevelam. These studies lasted 8 to 26 weeks. Only one small study compared colesevelam directly to placebo, the other five studies investigated a combination of colesevelam with other antidiabetic agents versus a combination of placebo with other antidiabetic agents. There were no two studies with the same intervention and comparison group. When added to other antidiabetic agents colesevelam showed improvements in the control of blood glucose and blood lipids. However, it is difficult to disentangle the effects of colesevelam from the other antidiabetic agents used because only one study compared colesevelam to placebo. The same is true for adverse effects: three studies reported on just a few non-severe hypoglycaemic episodes, no other serious side effects were observed. No study investigated mortality; complications of type 2 diabetes such as eye disease, kidney disease, heart attack and stroke; health-related quality of life; functional outcomes and costs of treatment. Therefore, long-term data on the efficacy and safety of colesevelam are necessary.

Keyword: Lipids; Diabetes mellitus.