Patient summary

Trial title: A phase III, multi-centre, double-blind, placebo-controlled randomised trial to assess the clinical and cost-effectiveness of atorvastatin in patients with operable oesophageal adenocarcinoma (STAT-ROC2).

Background

Patients with the most common cancer of the food pipe in the UK, oesophageal adenocarcinoma (OAC), generally have a very poor outlook. Even in those who have potentially curative initial treatment (with surgery +/- chemotherapy) the cancer often returns and only 45% survive to three years. Effective, safe and well-tolerated treatments to prevent cancer recurrence in patients with this cancer are urgently required. There is evidence that statins, medications used to treat high cholesterol and prevent heart disease and strokes, have anti-cancer effects. Laboratory studies have shown that statins reduce growth and survival of OAC cells and may limit their ability to spread to other organs. Large studies in patients with cancer (including OAC) show that patients taking statins after diagnosis have improved survival times. Although this evidence is encouraging, a clinical trial is needed as proof.

Aim

We wish to find out whether atorvastatin 80mg (a potent statin) taken once daily for up to three years after surgery for OAC prevents recurrent cancer and improves survival. We will also find out if statins represent good value for money for the NHS.

Design and Methods

Our research team has recently completed an NIHR-funded feasibility trial (STAT-ROC1) in patients from four UK hospitals. This study has shown that a future trial (STAT-ROC2) is feasible and gives valuable information on how it should be carried out. STAT-ROC2 is a large UK clinical trial involving patients with OAC or tumours of the area joining gullet and stomach who are due potentially curative surgery. Patients will be asked to join the study before their operation. Following surgery, willing patients will be prescribed atorvastatin 40mg for two weeks. If the medication is well-tolerated and provided patients take it regularly then patients will be randomised to receive either atorvastatin 80mg or an identical placebo tablet. The study will decide which medication the patient will receive. Patients will receive study medication for up to three years. Neither patients, researchers, nor their consultants will know which medication they are taking until the end of the study. Patients will have research visits, organised to coincide with their regular clinical follow-up after surgery for up to three years. These visits will be held every three months for the first year and every six months thereafter for the remaining two years. Each research visit is expected to last up to one hour and will include bloods tests for safety, completion of quality of life questionnaires and an assessment for potential side effects. Patients will be follow-up in person for up to three years and for up to five years using routinely-collected healthcare databases. We plan to recruit 568 patients over three and a half years. The study is planned to start in 2018 and complete in 2025. Patient survival and cancer recurrence will be compared between those allocated to atorvastatin and placebo.

Patient and public involvement

The design, conduct and dissemination of this study has been planned in collaboration with previous STAT-ROC participants and their relatives, the Norwich Branch of the Oesophageal Patients' Association and regional cancer charities.