

Comparing open and minimally invasive surgical procedures for oesophagectomy in the treatment of cancer: the ROMIO (Randomised Oesophagectomy: Minimally Invasive or Open) feasibility study and pilot trial

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Plain English summary

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The survival of some patients with oesophageal (gullet) cancer can be improved by surgery (oesophagectomy). Surgery traditionally requires large incisions to be made in the abdomen, the chest and sometimes the neck (open surgery). Complications are common and recovery takes ≥ 6 months. Minimally invasive 'keyhole' surgery may achieve the same survival benefit, with quicker recovery. However, to confirm this, a randomised controlled trial (RCT) needs to be carried out to make a fair comparison between the surgical approaches. The present study conducted preparatory work in a small RCT in two departments of surgery.

This trial indicated the feasibility of a full-scale evaluation, with 104 patients agreeing to take part over 21 months. The random allocation of a surgical approach to each patient resulted in similar groups of patients undergoing the different approaches, which, with most patients undergoing their allocated surgery (87%), ensured a fair comparison between the approaches. By bandaging all possible incision points for the first week post surgery, it proved possible to keep patients from knowing which surgical approach they had undergone, improving the assessment of postsurgical pain. Participants are reporting, with high completion rates, on outcomes such as physical function and fatigue over a 3-year period. Patients and clinicians are being consulted on the most important measures of outcome following oesophagectomy. The steps in performing an oesophagectomy have been documented, including the important differences between the approaches, allowing quality control of surgery. Finally, the important costs and methods of measurement have been determined, allowing a cost-effectiveness analysis in the full-scale evaluation.

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