A randomised controlled trial comparing the clinical effectiveness and cost-effectiveness of laparoscopic cholecystectomy compared with observation/conservative management for preventing recurrent symptoms and complications in adults with uncomplicated symptomatic gallstones (C-Gall)

Record Status
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Citation
A randomised controlled trial comparing the clinical effectiveness and cost-effectiveness of laparoscopic cholecystectomy compared with observation/conservative management for preventing recurrent symptoms and complications in adults with uncomplicated symptomatic gallstones (C-Gall) Health Technology Assessment

Authors' objectives
Gallstones are common, especially in women, but in many people they do not cause any symptoms. About one in three people with gallstones develop symptoms. Symptoms usually include a severe pain in the upper right-hand side of the abdomen (known as biliary colic), and sometimes nausea and vomiting. At times the pain is accompanied by inflammation of the gallbladder (cholecystitis). Once gallstones start giving symptoms, painkillers, anti-inflammatory medicines and antibiotics are usually prescribed initially and surgery is advised to medically fit patients. Surgery to remove the gallbladder, known as cholecystectomy, is the most common way to treat biliary pain or cholecystitis due to gallstones. Approximately 70,000 cholecystectomies are performed every year in the UK, with significant costs for the NHS. In the UK, surgery is commonly offered to people who present at secondary care with pain or cholecystitis due to gallstones. However, it is known that some patients do not have any more symptoms after the initial episode of pain and that surgery may not be necessary. A policy of conservative management (painkillers/antibiotics and lifestyle advice) could, therefore, be appropriate in this group of people. A review of current evidence suggested that conservative management may provide a more efficient use of NHS resources. There were, however, great uncertainties in the data, with only two small studies run in Norway. There is a need for a definitive clinical trial to address these uncertainties. The study proposed here will identify patients for the trial at hospital settings for people referred by general practitioners with symptomatic gallstone disease. Patients will be recruited following informed consent to participate using processes approved by an NHS Research Ethics Committee. Once consented, the patient will be allocated randomly to either receive a surgical procedure to remove the gallbladder or to receive conservative management. Apart from treatment allocation and measurement of study outcomes, participants will have standard NHS follow up. Based on statistical calculations, we aim to recruit 430 participants over one and half years who will be followed up for at least 18 months across 20 UK hospitals. The main outcome of the study will be the difference between the two policies in the patients quality of life across an 18 month period from enrolment. We will assess this using a specifically designed questionnaire. To assess any longer term benefits of either policy we will use a mathematical model to give a prediction of quality of life over each participant’s lifetime. We will use the measurements we collect and the model to work out whether gall bladder removal is worthwhile to the NHS in terms of balancing any benefit to people’s health against the added costs (cost-effectiveness). The results of this study will enable patients, clinicians and policy-makers to decide the worth of conservative management as part of treatment of uncomplicated gallstone disease. We have assembled a national team of experts with experience in carrying out clinical trials of surgical procedures, including surgeons, trial methodologists, statisticians, economists and trial managers. The team also benefits from the valuable insight of a knowledgeable patient user group that will continue to be closely involved as the trial progresses. The funding will support essential staff and research resources necessary for this trial.

Project page URL
http://www.nets.nihr.ac.uk/projects/hta/1419271

Indexing Status
Subject indexing assigned by CRD