

COMICS was an international clinical trial which aimed to compare two different heart-lung machines, which are used to take over the function of the heart when patients have heart surgery. During heart surgery, the blood which usually flows through the heart is instead passed through a heart-lung machine, which keeps the blood full of oxygen and flowing around the body. The most common machine is a 'conventional extracorporeal circuit'. A new smaller machine, a 'minimally invasive extracorporeal circuit', has been developed with the aim of reducing serious complications after heart surgery, for example heart attack, stroke, kidney failure or death.

The heart-lung machine is necessary for the surgeon to do the surgery, but can also cause rare but serious complications. COMICS focused on 12 serious complications of heart surgery associated with using a heart-lung machine. The trial aimed to compare the number of people experiencing any of these complications when having heart surgery with either the 'conventional' or smaller machine. The trial also looked at the numbers of patients who died and who experienced other serious complications not associated with using the heart-lung machine.

Patients took part in the trial between May 2018 and December 2021, and were recruited from hospitals in Canada, England, Germany, Greece, Italy, Saudi Arabia, Switzerland and Turkey. Patients could take part if they were aged ≥ 18 and < 85 years and booked for urgent or elective heart surgery using a heart-lung machine. Following consent, patients were assigned at random to have surgery using one or the other of the two machines. All other aspects of their care was the same. The trial collected information relating to patients' operations and hospital stay. After surgery, patients were asked to complete questionnaires relating to quality of life and hospitals provided details of any admissions in the 30 days after the operation.

Unfortunately, due to the COVID-19 pandemic, COMICS stopped earlier than planned. 1071 patients took part in the trial rather than the planned number of 3500. This means that the findings of the trial are more uncertain than we had hoped. Nevertheless, the trial found that heart surgery using the new, smaller machine reduced the number of serious complications which patients had by 25%, when compared to the 'conventional' machine. The smaller machine also seemed to reduce the risk of death and any other serious complication by about 20% but these results were even more uncertain. Finally, the smaller machine slightly improved the quality of life reported by patients after surgery.

This trial adds to evidence that the smaller machine is safe to use and can improve patient quality of life after heart surgery. However, the patients who took part in COMICS tended to be relatively well at the time of surgery when compared to all patients having heart surgery. The results of this trial are being reviewed for publication.

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