# Robotic versus laparoscopic surgery for severe deep endometriosis: protocol for a randomised controlled trial (ROBEndo trial)

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BMJ Open. 2022 Jul 18;12(7):e063572. doi: 10.1136/bmjopen-2022-063572.

## Abstract

**Introduction:**Endometriosis is a common gynaecological disease affecting around 10% of fertile-aged women, causing severe pain symptoms. Deep endometriosis is defined as endometriotic implants that infiltrate the underlying organs more than 5 mm in depth. Surgery for deep endometriosis requires advanced multidisciplinary surgical technique, often in very difficult surgical conditions, with increased risks of complications. Robotic surgery offers a high-definition three-dimensional view and articulating instruments that may allow more precise dissection than conventional laparoscopy in the pelvic area. The superiority of robotic surgery has not, however, been provedin randomised controlled studies, and there is a lack of long-term outcome data. Advanced endometriosis surgery offers an excellent platform to study the feasibility and long-term outcomes of robotic surgery compared with conventional laparoscopy.

**Methods and analysis:**ROBEndo is a prospective, randomised, controlled clinical trial in a single-centre setting. Patients with deep endometriosis verified by MRI needing surgery at Oulu University Hospital (Oulu, Finland) will be considered eligible. 70 patients will be allocated 1:1 to receive either robotic-assisted or conventional laparoscopic surgery in two strata: radical surgery (with the removal of the uterus and adnexae) and gynaecological organ-sparing surgery. The primary outcome will be the surgical outcome as regards to pain symptoms measured on numeric rating scale (NRS) questionnaires at 24 hours and 6, 12 and 24 months postoperatively. As secondary outcomes, intraoperative measures, enhanced recovery after surgery factors, complications, cost and long-term quality of life measured with Endometriosis Health Profile-30 (EHP-30), Female Sexual Function Index (FSFI) and 15-dimensional (15D) questionnaires will be compared.

**Ethics and dissemination:**This study has been approved by the Northern Ostrobothnian Hospital District Ethical Committee at Oulu University Hospital (212/2021). Informed consent will be obtained during the preoperative check-up by the operating gynaecologist. The results will be published in peer-reviewed international journals.

**Trial registration number:**[NCT05179109](http://clinicaltrials.gov/show/NCT05179109).

**Keywords:**Adult surgery; GYNAECOLOGY; Minimally invasive surgery.