OPT trial: A Randomized Controlled Trial of Outpatient Polyp Treatment for Abnormal Uterine Bleeding

Background

Abnormal uterine bleeding is one of the four most common reasons for consulting a GP. Uterine polyps are outgrowths of the endometrial lining that can occur anywhere within the womb cavity.

With the advent of high-resolution pelvic ultrasound and hysteroscopic (internal camera) diagnosis, it has become clear that abnormal bleeding is associated with uterine polyps in between 20-30% of cases in both pre and post-menopausal women. Most gynaecologists perform a hysteroscopy beforehand to locate the polyp then surgically remove the polyp under general anaesthetic.

The miniaturisation of hysteroscopes and surgical equipment, coupled with enhanced imaging, has enabled hysteroscopic surgery to be performed in an outpatient setting without the need for general anaesthesia or inpatient hospital admission. Uterine polypectomy is a safe and technically successful procedure for the treatment of abnormal uterine bleeding but there is a lack of evidence on the relative benefits of outpatient polyp treatment (OPT) compared to traditional inpatient approaches in terms of feasibility, patient acceptability or cost-effectiveness.

What was the OPT study?

The OPT study aimed to address the hypothesis that in women with abnormal uterine bleeding associated with benign uterine polyps, OPT achieves as good, or no more than 15% worse, alleviation of bleeding symptoms compared to standard inpatient treatment at six months after the procedure.

OPT was a pragmatic multicentre randomized controlled equivalence trial of outpatient versus in-patient polypectomy, with a concurrent non-randomized cohort of women with a strong preference for treatment setting.

What did the OPT study find?

The OPT study recruited 507 women between April 2008 and May 2011, and all women have now completed their 12 month follow-up. Interviews with women who had either in- or out-patient treatment have been undertaken and analysed.
The data are being analysed and the results will be submitted for publication by the end of 2012.

What impact will this study have?

If OPT is as effective as the removing polyps as in-patient surgery, women will be able to avoid a general anaesthetic and be managed in a “see and treat” appointment. Thus OPT offers potential advantages to women and their doctors in terms of convenience and choice. The OPT trial will provide the evidence on the effectiveness, cost-effectiveness and acceptability of OPT.

Protocol

Version 2.2 of the OPT Protocol dated 20.10.2009 (/Documents/college-mds/trials/bctu/opt/OPT-Pro-V22.pdf)

Publications

This study was funded by the NIHR Health Technology Assessment programme.
http://www.hta.ac.uk/project/1679.asp (http://www.hta.ac.uk/project/1679.asp)

More information

Wellbeing of Women (external link)
http://www.wellbeingofwomen.org.uk/downloads/file/00_friends_area/WoW_INFO_BOOKLET.pdf
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