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A randomised controlled trial of outpatient polyp treatment for abnormal uterine bleeding

Submission date
11/10/2007

Recruitment status
No longer recruiting

Registration date
15/11/2007

Overall study status
Completed

Last Edited
21/04/2016

Condition category
Urological and Genital Diseases

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Uterine polyps are small, soft, outgrowths from the lining of the womb (the uterus). In the majority of cases, the polyps are benign and are not cancerous. Symptoms include bleeding between periods, after sexual intercourse, or intermittent bleeding after the menopause. Polyps are usually diagnosed by ultrasound or by hysteroscopy (looking into the womb via the vagina with a long fine telescope). Polyps require investigation and can be treated in an outpatient clinic where they are removed with forceps under local anaesthetic. Alternatively, a general anaesthetic may be given to investigate the inside of the uterus and remove polyps. Currently, most doctors only offer the in-patient, general anaesthetic option but increasingly more will perform the outpatient polyp treatment (OPT). However, it is not known which method is better at removing polyps and improving the bleeding symptoms, or indeed which is preferred by women or is cheaper for the NHS. The aim of this study is to compare the effectiveness of OPT with the in-patient approach.

Who can participate?
Women who have irregular uterine bleeding caused by benign polyps that are suitable for removal by either approach

What does the study involve?
Participants are randomly allocated to either have the OPT straight away or to come back to the hospital as an in-patient. Before the hysteroscopy, women complete a questionnaire to rate the amount of bleeding they have, their sexual activity and their general quality of life, and again at 3, 6 and 12 months after treatment. Some of the participants are interviewed about how they feel about their treatment. The doctor records information about the completeness of polyp removal and any surgical complications or repeat procedures. Some of the participants are also asked to have a second hysteroscopy at 6 months to confirm whether the polyp has returned.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Birmingham Women's Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2008 to September 2013

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
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Study website
http://www.opt.bham.ac.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 06/404/84

Study information

Scientific Title
A randomised controlled trial of Outpatient Polyp Treatment for abnormal uterine bleeding

Acronym
OPT

Study objectives
Abnormal uterine bleeding is one of the four most common reasons for consulting a general practitioner and accounts for 70% of all referrals to hospital gynaecology clinics, making this complaint one of the commonest problems in gynaecology. With the advent of high-resolution pelvic ultrasound and hysteroscopic diagnosis, it has become clear that abnormal bleeding is associated with uterine polyps in between 20-30% of cases. This pattern is found to affect both pre- and postmenopausal women across all age groups. The improved diagnostic accuracy has led to the increased use of surgical intervention for the removal of polyps (polypectomy), a procedure that is universally practised to resolve symptoms and to obtain tissue for histological examination.

Added 01/09/2011:
To test the hypothesis that in women with abnormal uterine bleeding associated with benign uterine polyp(s), outpatient polyp treatment (OPT) achieves as good, or no more than 25% worse (i.e. 90% successful v 67% successful), alleviation of bleeding symptoms compared to standard inpatient treatment at six months (principal objective).

(Previous hypothesis at time of registration: In women with abnormal uterine bleeding associated with benign uterine polyp(s), does Outpatient Polyp Treatment (OPT) achieve as good, or no more than 15% worse, alleviation of bleeding symptoms compared to standard inpatient treatment at six months?)

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/0640484
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0014/51413/PRO-06-404-84.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Research Ethics Committee, 15/02/2008, ref: 08/H0206/6

Study design
Randomised controlled multi-centre equivalence trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information material can be found at: http://www.download.bham.ac.uk/bctu/OPT/Trial%20Documentation_Consent%20PIS%20and%20GP%20Sheets/OPT%20PIS%20Version%201.3%20230408.pdf

Health condition(s) or problem(s) studied
Abnormal uterine bleeding associated with a benign polyp

Interventions
Current interventions as of 01/09/2011:
Outpatient polypectomy will be performed immediately following diagnosis at outpatient hysteroscopy in most instances, although some participants may have their outpatient treatment scheduled to a later date, depending upon local circumstances, within the following 8 weeks, as not all clinics are able to offer
immediate 'see & treat' outpatient treatment. Polyp removal will be carried out under direct hysteroscopic vision using miniature mechanical or electrosurgical instruments, with or without the need for minor degrees of cervical dilatation and local anaesthesia (direct cervical infiltration or paracervical injection). Occasionally blind avulsion with small polypectomy forceps after hysteroscopic localisation may be required.

Inpatient polypectomy will be performed within 8 weeks of the initial diagnosis at outpatient hysteroscopy. Inpatient polypectomy will be performed by traditional dilatation and endometrial curettage ('D&C'), blind avulsion with or without prior localising hysteroscopy or under direct vision using an operative hysteroscope.
In most instances, wide dilation of the cervical canal will be required to accommodate the larger diameter inpatient instruments within the uterus. General or spinal anaesthesia facilitates major degrees of cervical dilatation and manipulation of these larger diameter instruments within the uterine cavity.

Previous interventions:
Outpatient uterine polypectomy will be performed under direct hysteroscopic vision using miniature mechanical or electrosurgical instruments with or without the need for minor degrees of cervical dilatation. Occasionally blind avulsion with small polypectomy forceps after hysteroscopic localisation may be required.

Inpatient uterine polypectomy will be performed by traditional Dilatation and endometrial Curettage (D&C), blind avulsion with or without prior localising hysteroscopy or under direct vision using an operative hysteroscope. In most instances, wide dilation of the cervical canal will be required to accommodate the larger diameter inpatient instruments within the uterus. General anaesthesia facilitates major degrees of cervical dilatation and manipulation of these larger diameter instruments within the uterine cavity.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measure as of 01/09/2011:
The patient's own assessment of bleeding symptoms at 6 months, using a dichotomous outcome measure, will be used to establish if the treatment has been successful. The question used for this measure will be dependent on whether the patient is pre or post-menopausal, predominant complaint at randomisation and type of HRT they may be using. Further details can be seen in Figure 2 (protocol v2.2 page 9). In all cases a 'yes' response will be defined as a success.

Previous primary outcome measure:
Abnormal uterine bleeding (post-menopausal, unscheduled bleeding on Hormone Replacement Therapy [HRT]/tamoxifen or intermenstrual bleeding) at 6 months measured by visual analogue scale (0 = no bleeding; 10 = continuous bleeding)

Secondary outcome measures
Current secondary outcome measures as of 01/09/2011:
The following secondary outcomes will be assessed by a booklet sent to the women at home containing questionnaires/questions at baseline, 6, 12 and 24 months post-randomisation:
1. Shaw Menorrhagia assessment scale A multi-attribute utility, designed to measure the impact of heavy menstrual bleeding (menorrhagia) upon HRQL
2. Likert scale. All patients will be asked how their bleeding has responded to treatment using a Likert scale with four response options
3. Health related quality of life measured by EuroQol EQ-5D Instrument
4. Visual analogue scale (VAS) It is now well established that objective measures of blood loss are not particularly relevant to women's subjective perception of bleeding symptoms

Previous secondary outcomes measures:
The following secondary outcomes will be assessed by a booklet sent to the women at home containing questionnaires/questions at baseline, 3, 6, 12 and 24 months post-randomisation:
1. Abnormal uterine bleeding (as above) measured at 3, 12 and 24 months
2. Health related quality of life measured by the multi-attribute utility menorrhagia assessment scale (if type of abnormal uterine bleeding is menorrhagia)
3. Satisfaction with treatment outcome
4. Sexual function measured by Sexual Activity Questionnaire
5. Health related quality of life measured by EuroQol EQ-5D Instrument
6. Patient anxiety and preference at baseline
7. Patient acceptability of uterine polypectomy (OPT vs inpatient treatment)
8. Data on economic endpoints (i.e. health resource utilisation e.g. general practice and hospital visits, days off work etc.) at 3, 6 and 12 months
9. Other measures will include information on technical feasibility (baseline) and complications of surgery (baseline, 3, 6 and 12 months). In addition we will perform a follow-up diagnostic outpatient microhysteroscopy at six months to assess completeness of treatment. The uterine cavity will be examined for persistence or recurrence of uterine polyp(s) and the presence of iatrogenic uterine adhesions.

Overall study start date
01/04/2008

Completion date
30/09/2013

Eligibility

Key inclusion criteria
1. Abnormal uterine bleeding requiring diagnostic microhysteroscopy
2. Finding of a benign polyp (glandulocystic or pedunculated/grade 0 fibroid) on diagnostic microhysteroscopy
3. No hysteroscopic features suspicious of malignancy
4. Need for polypectomy

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
480

Key exclusion criteria
1. Hysteroscopic features suggesting malignant lesion
2. Additional pathology necessitating hysterectomy

Date of first enrolment
01/04/2008

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birmingham Women's Hospital
Birmingham
United Kingdom
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Sponsor information

Organisation
University of Birmingham and Birmingham Women's NHS Foundation Trust (UK)

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Sponsor type
University/education

ROR
https://ror.org/00xe5zs60

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2015		Yes	No