An Evaluation of a Doppler-Guided Uterine Artery Occlusion Device (D-UAO) as Treatment for the Reduction of Fibroid-Associated Symptoms

Published: 24-07-2007
Last updated: 08-05-2024

The primary objective of this study is to evaluate the safety and effectiveness of Doppler guided Uterine Artery Occlusion (D-UAO) as treatment for the reduction of fibroid-associated symptoms.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	Interventional

Summary

ID

NL-OMON31776

Source
ToetsingOnline

Brief title
The D-UAO study

Condition

- Menstrual cycle and uterine bleeding disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
Uterine Fibroids

Research involving
Human

Sponsors and support

Primary sponsor: ETHICON _ Johnson & Johnson MEdical Ltd
Source(s) of monetary or material Support: Ethicon;Johnson&Johnson

Intervention

Keyword: UterusFibroid-Associated symptomsArtery OcclusionDoppler-Guided

Outcome measures

Primary outcome

The primary effectiveness endpoint will be the percentage of subjects with the following definition of individual success at 12-months: *Lack of surgical re-intervention. Surgical re-intervention is defined as hysterectomy, Uterine Artery Embolisation (UAE), laparoscopic uterine artery occlusion, endometrial ablation, myomectomy (open, laparoscopic, hysteroscopic), endometrial resection, or myolysis by any method (including but not limited to: cryomyolysis, cautery, ultrasound, or laser).The primary safety endpoint is the incidence of adverse device effects (defined as related to the device) that result in any of the following treatments or outcomes:*Ureteral stenting;*Intra-operative or post-treatment blood transfusion;*Unintended major surgical procedure related to treatment;*Device-related re-hospitalisation greater than 24 hours;*Interventional treatment within 6-weeks of the D-UAO procedure;*Outpatient treatment of significant new medical problems, related to treatment;*Deep vein thrombosis (DVT) or pulmonary embolism (PE);*Life-threatening cardiac or respiratory arrest or other life-threatening events;*Death.

Secondary outcome

*SYMPTOM IMPROVEMENToPercentage of subjects with improvement in Uterine Fibroid Symptom Quality of Life (UFS-QOL) Symptom Severity and Health Related Quality of Life (HRQL) scores at 6, 12 and 24 months. Symptom severity response defined as a change of *11 in the transformed score and HRQL response defined as a change of +12 in the transformed score. oMean improvement in UFS-QOL Symptom Severity and HRQL transformed scores at 6, 12 and 24 months.oMean HRQL subscales at 6, 12 and 24 months.*REDUCTION IN BLEEDINGoPercentage of subjects with reduction of 50% or greater in Pictorial Blood Loss Assessment Chart (PBLAC) score at 6 and 12 months.oMean change in PBLAC scores from baseline to 6 and 12 months. *PROCEDURAL SUCCESS oPercentage of subjects with decrease in fibroid load at 6 months based on independent MRI review.oPercentage of subjects with maintenance of menses as defined by continuation of menstrual cycles without an interruption of three consecutive months at 12-months. oPercentage of subjects with procedural satisfaction as defined by responses of either satisfied or very satisfied at 12-months. *HEALTH ECONOMICS oPain score at discharge or 24-hour post clamp removal, whichever is earlieroDays to normal activities (household, work and sexual intercourse)oEuro-QOL at 1, 3, 6 and 12 months expressed as change from baseline for each of the 6 domains and Visual Analogue Scale (VAS) oNights in hospital (Total and post procedure)

Study description

Background summary

Background:Uterine fibroids are the most common solid pelvic tumor in women, estimated to occur in 77% of women of reproductive age1. Patients with

fibroids commonly present with menorrhagia2-4 and pelvic pressure symptoms. The physical, emotional, and social lives of fibroid patients are negatively affected.Vascular Control Systems (VCS) developed and manufactured the Doppler-Guided Uterine Artery Occlusion Device (D-UAO) and conducted the initial clinical studies as discussed in later in this section. ETHICON CDMA is the sponsor for this study. Alternative Treatments:Hysterectomy: Historically, hysterectomy has been performed as the definitive treatment for symptomatic fibroids symptoms providing complete and effective relief of symptoms. Using Center for Disease Control and Prevention data5 and a cohort study6 would predict 234,000 hysterectomies for fibroids in 2002. Symptom relief following hysterectomy has been associated with a marked improvement in quality of life.6,7 This surgical procedure does present many risks with complications including death, transfusions, deep vein thrombosis, intra-abdominal abscess, surgical wound abscess, sepsis, bowel or bladder trauma requiring repair, pulmonary embolism/infarct, myocardial infarction or cardiac and/or respiratory arrest.8 Hysterectomy is also associated with lengthy hospital stays and longer recovery. Myomectomy: Myomectomy has become a surgical alternative to hysterectomy for conservation of the uterus for reproductive or non-reproductive reasons. Although not a global uterine treatment, myomectomy typically removes more than one fibroid and provides symptom reduction.9,10 Myomectomy is plagued with high fibroid recurrence rates9,10 and with small bowel adhesions.11,12 Thus, myomectomy successfully relieves the symptoms of fibroids, but it does not affect the underlying process.13Drug Therapy: Drug therapy with gonadotropin-releasing hormone (GnRH) agonist therapy has been used to shrink uterine fibroids prior to myomectomy by suppressing estrogen and progesterone production and by the direct effect of GnRH agonist on fibroid tissue. Even though GnRH agonists can temporarily shrink fibroids, the suppression of ovarian production of estrogen and progesterone causes patients treated with GnRH agonists to experience the unpleasant symptoms of menopause. Letterie et al14 reported the rate of GnRH agonist related side-effects including hot flashes (78%), vaginal dryness (32%) and transient frontal headaches (55%). Despite a significant decrease in uterine and fibroid volume and decrease in menorrhagia while on therapy, fibroid and uterine volumes rapidly return to pre-treatment sizes and menorrhagia recurs in all patients within one or two months after discontinuing GnRH agonist therapy. GnRH agonists, thus, only provide temporary relief from fibroid symptoms. Uterine Artery Embolization: Bilateral uterine artery embolisation (UAE) is an angiographic, uterine sparing procedure designed to stop blood flow to the uterus. This procedure, performed by interventional radiologists, involves catheterization of both uterine arteries under fluoroscopic (x-ray) visualization, and injection of either polyvinyl alcohol (PVA) particles or acrylic co-polymer (trisacryl) cross-linked with gelatin. Three-month data on 538 women from the Ontario Uterine Fibroid Embolisation Trial showed significant improvements in fibroid-related symptoms including menorrhagia.15 Many publications have reported complications from particles flowing to organs and tissues other than fibroids. For example, embolic particles intended to reach the uterus instead reached the buttocks resulting in gluteal muscle

pain16 and ischemia17 as well as necrosis.18 Ryu et al19 reported complete loss of detectable ovarian arterial circulation in the majority of patients undergoing UAE. When the plastic particles are on target, embolization has also resulted in serious adverse events relating to diffuse uterine necrosis requiring hysterectomy.20 Patient deaths have also been reported as a result

of uterine artery embolization.21-25 These studies suggest that UAE of the uterine arteries is a successful treatment option for symptomatic uterine fibroids, but the adverse events are numerous, widespread, and can be fatal.ExAblate® 2000: The ExAblate 2000 employs a focused ultrasound beam that heats and destroys the uterine fibroid tissue using high-frequency, high-energy sound waves. This system, operated by a radiologist, uses magnetic resonance imaging (MRI) and a thermal mapping system to visualize patient anatomy, map the volume of fibroid tissue to be treated, and monitor the temperature of the uterine tissue after heating. This device is not recommended for fibroids near sensitive organs such as the bowel or bladder. Initial results show a mean fibroid shrinkage rate of 13.5% at 6 months with a 79.3% reduction in the symptoms.26 Total uterine volume results were not reported. Adverse events described with the ExAblate 2000 system included nerve injury/leg pain, bowel symptoms, bladder symptoms and skin injury. Effects on the composition and strength of the uterine tissue are not completely understood.27Previous Clinical Experience:The following discussion describes clinical experience in human subjects with the Transvaginal Doppler Clamp design. One feasibility study and two clinical studies have been conducted with the 510(k) cleared Transvaginal Doppler Clamp in Canada and the U.S. under a Research Ethics Board or Institutional Review Board approval, respectively. Review Board requirements have been followed. Informed consent was received from all enrolled subjects. Health Canada approval was obtained for the Canadian studies. In all three studies, the subject population consisted of women with symptomatic uterine fibroids seeking treatment. Changes in bleeding symptoms and general quality of life were assessed by the (Ruta) Menorrhagia Severity Scale28 and the SF-12, respectively. VCS026 Clinical Evaluation (St. Joseph*s Health Care in London, Ontario, Canada)Seventeen (17) subjects ranged in age from 32 to 51 years (mean 43.2 years) with uterine fibroids, menorrhagia, pelvic pressure/pain, dysmenorrhea, and bladder and bowel dysfunction present. The ability to locate and occlude the uterine arteries was achieved in all 17 subjects by loss of audible Doppler signal. Procedural success occurred in 16 of 17 (94%) subjects; average clamp time of the 17 subjects was 5.8 hours (range 0.7 to 7.0 hours). One subject experienced a reaction to the anesthesia and did not complete the procedure; review of this case necessitated a change in the anesthesia type for the procedure. Inspection of the vaginal tissue following clamp removal indicated no damage to the surrounding tissue in a majority of the subjects (75% or 12 of 16); the remaining subjects had light bruising or vaginal edema. The majority of subjects (59% or 10 of 17) in the feasibility study did not experience any adverse events. The remaining 7

subjects had 9 events. Onset of seven events occurred within 2 weeks post-procedure. Prophylactic medications were not prescribed at this site. In addition to the anesthesia reaction discussed above, events included two urinary tract infections (resolved 13 and 25 days after onset), back pain (resolved 11 days after onset), and suprapubic pressure and urgency secondary to fibroid ischemia (resolved 74 days after onset). Thirty days after the procedure, one subject developed pain with menses (resolved 63 days after onset). Finally, one subject first noted worsened bulk effects at the 6-month follow-up visit; no further information on resolution is available.Two events of hydronephrosis occurred in two subjects. Subject 007 developed left hydronephrosis post-procedurally; a renal ultrasound 47 days later indicated spontaneous resolution. (Note: This subject also had pre-existing right hydronephrosis. As the hydronephrosis remained unchanged after the procedure, it is not considered an adverse event.) Subject 001 developed hydronephrosis on the day of the procedure that was not confirmed as r

esolved until 200 days later. One month after the procedure, all symptoms had subsided. At 53 days, the clinician and radiologist consult did not recommended further follow-up based upon an essentially normal renal ultrasound. A Sponsor-recommended renal ultrasound confirmed resolution at 200 days. Subject 001 did not have any clinical complaints of the hydronephrosis during this time.Efficacy analyses results are initially stated for the overall study population mean of individual subject changes from the baseline to 6-month follow-up period. Results then classify *Responders* (subjects with individual changes of 5% or greater). Six-month follow-up on 14 of 16 feasibility study subjects indicated encouraging changes. Bleeding symptoms were assessed by the Menorrhagia Severity Scale. Overall, the mean change was a 41% symptom reduction. Responders (11 of 14 subjects or 79%) experienced a 54% mean symptom reduction (range -78% to -18%). The study population demonstrated substantial mean point improvement in general health over gender-matched norms. The SF-12 Physical Component Summary mean increased from 1.6 points at baseline to 4.5 points at 6 months. The SF-12 Mental Component Summary mean increased from 0.1 point at baseline to 4.3 points at 6 months.Objective measures included transvaginal ultrasound and MRI. On transvaginal ultrasound, dominant fibroid volume decreased 24%. Responders (8 of 13 subjects or 62%) experienced 56% mean volume shrinkage (range -90% to -7%). Uterine volume decreased 12%. Responders (8 of 14 subjects or 57%) experienced 32% mean volume shrinkage (range -74% to -6%). Final efficacy evaluation of the feasibility study was completed on MRI examination of 12 subjects. A post 6-month follow-up MRI was performed at a mean of 10.3 months (range 8.3 to 12.1 months). Overall, dominant fibroid volume decreased 24%. Responders (9 of 12 subjects or 75%) experienced 36% mean volume shrinkage (range -84% to -9%). Uterine volume decreased 3%. Responders (6 of 12 subjects or 50%) experienced 22% mean volume shrinkage (range -44% to -5%). VCS030 Clinical Evaluation (St. Joseph*s Health Care in London, Ontario,

Canada)Thirteen (13) subjects ranged in age from 35 to 49 years (mean 42.9 years) with uterine fibroids, menorrhagia, pelvic pressure/pain, pain during periods, and cramps. The ability to locate and occlude the uterine arteries was achieved in all 13 subjects by loss of audible Doppler signal. Procedural success occurred in all 13 subjects; average clamp time was 7.1 hours (range 6.0 to 9.0 hours). Inspection of the vaginal tissue following clamp removal indicated no damage to the surrounding tissue in all of the subjects. Thirty-eight percent (5 subjects) did not experience any adverse events. The remaining 8 subjects had 18 events. Onset of 11 of the 18 events occurred within 2 weeks post-procedure. Prophylactic medications were not prescribed at this site. Subject 004 experienced half of all the events including (in temporal occurrence from procedure) urinary retention that resolved with medication 5 days after onset, left hydronephrosis that resolved spontaneously 6 days after onset, right hydronephrosis (discussed below), edema of the thighs and labia that resolved 7 days after onset, two lower urinary tract infections that resolved with medications 10 and 11 days after onset, back pain, flank pain and difficulty voiding (discussed below). Other subject events included right hydronephrosis and flank pain (discussed below), bloating (resolved 2 days after onset), pinkish discharge (resolved 14 days after onset), cystitis (resolved 12 days after onset), mild discomfort and heavy bleeding (resolved 7 days after onset), urinary leakage/mild dysuria (resolved 30 days after onset), bloating (resolved 1 day after onset), and cramping (resolved 31 days after onset).Subjects 004 and 010 developed hydronephrosis post-procedurally that required further intervention. Repeat renal ultrasounds indicated worsening progression. Cystoscopy, right retrograde pyelogram and ureteral sten

t insertion was performed on both subjects. Both stents were removed and the subjects reassessed. Subject 010 had complete resolution of the hydronephrosis and associated flank pain after the stent removal. For Subject 004, the hydronephrosis and associated flank pain, back pain, and difficulty voiding continued after stent removal: A right ureteroscopy, laser endoureterotomy, and second ureteral stent placement were completed. Six months after the procedure, all events for Subject 004 had resolved.Six-month follow-up was obtained on all 13 subjects. All subjects were Responders with a Menorrhagia Severity score change of 42% bleeding symptom reduction (range -81% to -13%). On transvaginal ultrasound, dominant fibroid volume decreased 20%. Responders (9 of 13 subjects or 69%) experienced 44% volume shrinkage (range -82% to -11%). Overall, uterine volume decreased 21%. Responders (10 of 13 subjects or 77%) experienced 34% volume shrinkage (range -64% to -8%). On MRI, dominant fibroid volume decreased 29%. Responders (10 of 13 subjects or 77%) experienced 45% volume shrinkage (range -100% to -13%). Overall MRI uterine volume decreased 16%. Responders (10 of 13 subjects or 77%) experienced 24% volume shrinkage (range -39% to -12%). VCS025 Clinical Evaluation (Holy Cross Medical Group in Fort Lauderdale, Florida) Ten (10) subjects ranged in age from 34 to 49 years (mean 39.8 years) with uterine fibroids, menorrhagia,

prolapse, pelvic pressure/pain, bloating and urinary tenesmus, and irregular menses. The ability to locate and occlude the uterine arteries was achieved in all 10 subjects by loss of audible Doppler signal. Procedural success occurred in all 10 subjects; average clamp time was 6.2 hours (range 6.0 to 6.7 hours). Inspection of the vaginal tissue following clamp removal indicated no damage to the surrounding tissue in all of the subjects. The majority (7) of subjects (70%) did not experience any adverse events. The remaining 3 subjects had 3 events. Onset of all events occurred within 2 weeks post-procedure. Events including a spinal headache from the anesthesia (resolved the same day), left hydronephrosis (resolved 42 days after onset), and vaginal discharge (resolved 2 days after onset). Six-month follow-up was obtained on five subjects. Overall, the Menorrhagia Severity score reflected a 55% bleeding symptom reduction. Responders (4 of 5 subjects or 80%) experienced a 70% symptom reduction (range -88% to -63%). The study population demonstrated mean point improvement in general health over gender matched norms. The SF-12 Physical Component Summary mean increased from -0.3 points at baseline to 6.0 points at 6 months. The SF-12 Mental Component Summary mean increased from -4.4 points at baseline to 0.9 points at 6 months.Transvaginal ultrasounds results were available on only two subjects. Both subjects were Responders. Overall dominant fibroid volume decreased 10% and uterine volume decreased 15%. No post-procedure MRIs were completed for VCS-025.The Canadian Investigator informed the sponsor that two subjects in the feasibility study sought alternative treatment after the conclusion of the 6-month follow-up visits. The choice of alternative treatment was unrelated to safety or efficacy outcomes from the use of the Transvaginal Doppler clamp. One subject underwent a hysterectomy; the second a uterine artery embolization. Additionally, one subject within the Florida clinical study withdrew from the study prior to the 1-month visit and completed a myomectomy. No reports of complications as a result of the earlier Clamp treatment were indicated.

Study objective

The primary objective of this study is to evaluate the safety and effectiveness of Doppler guided Uterine Artery Occlusion (D-UAO) as treatment for the reduction of fibroid-associated symptoms.

Study design

This is a multicentre, prospective, single-arm study conducted at approximately 12 to 16 investigational sites in Europe. Endpoint analyses will be based upon 12-month data however there will be a 24-month follow-up visit to report re-intervention and safety data. Two interim analyses will be performed: 1) To review the safety data on the first 60 patients receiving ureteric flow evaluation (colour Doppler ultrasound and/or cystoscopy); 2) An interim descriptive analysis will be performed on 6-month data. Safety and effectiveness will be summarised using data from a minimum of 60 patients and

peri-operative data from all available patients. The primary effectiveness variable will not be evaluated.The anaesthesia administration for the study procedure will be either epidural or local anaesthesia. Patients will not be randomised to anaesthesia type, as this will be determined by the site's anaesthesia capabilities and the most appropriate anaesthesia for the patient.All subjects will have their bilateral ureteric flow evaluated by colour Doppler ultrasound or cystoscopy both before and immediately after bilateral uterine artery occlusion. Subjects with no flow visualized prior to clamping will be considered screening failures and will not undergo the procedure. If after bilateral artery occlusion, no ureteral flow is visualized, the clamb should be removed and the subject recorded as a treatment failure. The subject will be followed up for one month for safety evaluation.Any subject who requires unplanned intervention including placement of a ureteral stent due to hydronephrosis that is thought to be associated with the study procedure will be deemed to have clinically significant hydronephrosis. This category would not include subjects with hydronephrosis that spontaneously resolves without medical or procedural intervention.If the total number of cases with clinically significant hydronephrosis exceeds 5 cumulatively, sites will be notified to suspend subject enrolment and the events will be reviewed by an Independent Data Safety Monitoring Board (DSMB) composed of at least 3 individuals including at least 2 clinicians with experience in managing hydronephrosis and 1 graduate statistician. These individuals may not be employees of the sponsor and may not otherwise be involved in this clinical study.The recommendation of the DSMB will be used to arrive at a plan to halt or re-start the study. Regulatory Authorities and ethics committees in all study site countries will be provided with the sponsors plan following the DSMB review..

Intervention

Doppler Guided Uterine Artery Occlusion, Bilateral

Study burden and risks

Potential Benefits of Doppler Guided Uterine Artery Occlusion:The Doppler guided, mechanical device is intended for bilateral occlusion of the uterine arteries. Through a transvaginal approach, gynecologists can offer a treatment option with the following possible benefits and advantages.1.Reduces uterine fibroid symptoms.a.Reduces fibroid associated bleeding.b.Improves health related quality of life.c.Reduces fibroid bulk and associated bulk symptoms.2.Offers a minimally invasive, incision-less, and uterine-sparing treatment.3.Presents a minimal number and degree of observed adverse events from prior clinical experience.4.Does not prevent future treatments as no heat, particles, or energy are used to treat the patient and no portion of the device remains after the procedure. 5.Provides an alternative treatment option for gynecologists and their patients. Gynecologists are the primary physicians in

the medical care of women with symptomatic fibroids. Potential Risks of Doppler Guided Uterine Artery Occlusion:Gynecological procedures for the treatment of uterine fibroids are associated with certain risks. These risks are outlined in section 10 of the protocol. Additionally, there are potential risks that may be directly associated with the device. These risks are as follows:1.Hydronephrosis and associated symptoms are possible with device placement. In 4 of the 6 prior cases with hydronephrosis discussed above, the event was mild in degree, resolved spontaneously and the subject did not experience any symptoms. In the 2 remaining cases, a ureteral stent was necessary for resolution. To further reduce this risk, procedural mitigations and safety evaluations are present in this study. Procedural mitigations include retrograde bladder filling to displace ureters, restriction of excessive Clamp movement during placement and appropriate device size selection. Safety evaluations include ureter flow assessments and renal ultrasounds.2.Deep vein thrombosis (DVT) is possible due to the 6-hour anaesthesia usage, however, this event has not been observed in prior studies. Safety mitigations of pneumatic compression devices are present in this study to reduce this risk.3.Local tissue injury. Vaginal and cervical lacerations have occurred with the placement of the tenaculum and clamp devices. They have been insignificant, have healed well and are to be expected with the use of such mechanical devices.4.Urinary Tract Infection (UTI). Insertion of a catheter and clamp placement is associated with an increased risk of urinary tract infection. Patients may not be enrolled with active UTI. If the condition develops, it is typically managed with antibiotics.5.Clinical symptoms associated with uterine fibroid degeneration (e.g. diffuse abdominal pain, generalized malaise, anorexia, nausea, vomiting, low-grade fever, and leukocytosis and/or low back pain may occur). Some submucous fibroids that undergo degeneration following Doppler guided uterine artery occlusion treatment may spontaneously pass from the body per vagina or require removal by a gynecologist.Conclusion:Early clinical experience has demonstrated promising results. Subjects indicated a reduction in uterine fibroid symptoms and an improved quality of life. Dominant fibroid volumes decreased. A minimal number and degree of adverse events have been observed. Despite the potential risks mentioned above, the possible benefits warrant the need for further evaluation of this device. This investigation aims to evaluate the device in a controlled subset of subjects. The current design should be sufficient to support the study*s objectives.

Contacts

Public
ETHICON _ Johnson & Johnson MEdical Ltd

Kirkton Campus _ Simpson Parkway

EH54 0AB Livingston
UK
Scientific
ETHICON _ Johnson & Johnson MEdical Ltd

Kirkton Campus _ Simpson Parkway
EH54 0AB Livingston
UK

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1.25 to 50 years of age;2.Subject has a negative pregnancy test prior to the procedure. At the time of enrolment to the study, the subject has no intent of further childbearing and intends to use appropriate contraception throughout the first 12-months of the study period (unless sterilized);3.Normal pap smear within 36 months of study procedure;4.Normal endometrial biopsy within 36 months of study procedure;5.Cervix suitable for tenaculum placement as determined by pelvic exam (adequate length of cervix, absence of cervical fibroid/lower fibroid to prevent clamp placement); 6.At least one intra-mural uterine fibroid of greater than or equal to 3cm, and all fibroids with a diameter less than or equal to 8cm with a prevailing pathology (e.g., as opposed to adenomyosis) of fibroids determined through ultrasound; 7.Subject agrees to participate in the study, including completion of all study-related procedures and evaluations, and documents this agreement by signing the EC-approved informed consent.

Exclusion criteria

1.Pregnancy as confirmed by positive urine pregnancy test; 2.Menopausal as defined by elevated follicle-stimulating hormone (FSH) and oestradiol hormone levels as determined by the hospital local laboratory reference range criteria;3.Presence of an intra-uterine device

(IUD);4.Presence of only sub-mucosal fibroids or any pedunculated fibroids as determined by MRI, ultrasound or hysteroscopy; 5.Severe hydronephrosis as determined on renal ultrasound pre-procedurally; 6.Clinical history of any thromboembolic disease;7.Blood Urine Nitrogen (BUN) greater than 7.2mmol/L* and/or serum creatinine greater than 106*mol/L* unresolved with change in diet or hydration; 8.History of gynecologic malignancy, atypical endometrial hyperplasia, or chronic pelvic inflammatory disease;9.Pelvic mass outside the uterus other than uterine fibroids;10.Any current acute or chronic systemic infection or localized pelvic infection, including a urinary tract infection;11.Use of GnRH agonist or mifepristone within 6-months prior to the start of the study procedure unless used immediately prior to the procedure. 12.Using anticoagulation therapy (except over the counter treatments (e.g. aspirin)), or have an underlying bleeding disorder; 13.Unsuitable for MRI examination (e.g. severe claustrophobia, non-MRI-compatible implanted metalloid devices)14.Prior endometrial ablation, uterine artery embolisation, or uterine artery ligation;15.Poor procedural candidate due to medical conditions as determined by the investigator (e.g. anesthesia class, renal insufficiency, heart disease); and 16.If applicable, Grade 1 (no flow visualized) on ureter flow assessment. *or above applicable local lab normal values

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-08-2007
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Doppler-Guided Uterine Artery Occlusion Device;D-UAO
Registration:	No

Ethics review

Approved WMO Date:	24-07-2007
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL16244.029.07