Name of Project: Comparing MRgFUS versus UAE for Uterine Fibroids (FIRSTT)

Investigator(s). (Include phone numbers and email address, indicate PI and primary contact)
Investigator: Dr. Vanessa Jacoby
Research Coordinator and primary contact: Stephanie Lemp
Email: lemps@obgyn.ucsf.edu

Research question(s): What are the outcomes for women undergoing UAE versus MRgFUS? Are there differences in fibroid symptoms, adverse events, additional fibroid procedures, pain, direct and indirect costs, bleeding, and ovarian reserve?

Brief Background/Significance:
Uterine leiomyomas (myomas or fibroids) are benign clonal tumors arising from the uterine myometrium. Despite their clinical and economic importance, there is little evidence on which to base treatment decisions. Two minimally invasive therapies are approved by the Food and Drug Administration for treatment of leiomyomas in a variety of locations: uterine artery embolization (UAE) and magnetic resonance–guided focused ultrasound surgery (MRgFUS). Although studies have demonstrated effectiveness of both treatments, comparative or randomized trials involving MRgFUS have not yet been reported. Therefore, women interested in these nonsurgical treatment options lack key information to make an informed decisions about which treatment to undergo. This randomized trial of uterine artery embolization versus magnetic resonance guided focused ultrasound will provide gold standard data to guide clinical management decisions for women with fibroids.

Inclusion Criteria:
1. Women able to give informed consent and willing and able to attend all study visits
2. Premenopausal women at least 25 years of age
3. No evidence of High Grade SIL by pap smears or HPV testing within institutional guidelines
4. Agree to be randomly assigned treatment

Exclusion criteria:
1. Women actively trying for pregnancy or currently pregnant
2. Uterine size > 20 weeks
3. Prior abdominal myomectomy, UAE, or MRgFUS. Previous hysteroscopic or laparoscopic myomectomy for the removal of only pedunculated leiomyomas (as described in #17, below) will be allowed and evaluated on an individual basis to determine eligibility for treatment.
4. More than 6 fibroids > than 3 centimeters in maximal diameter
5. Allergy to either gadolinium or iodinated contrast
6. Implanted metallic device prohibiting MRI
7. Severe claustrophobia
8. BMI which prohibits subject from fitting in MRI device
9. Severe abdominal scarring precluding safe MRgFUS treatment
10. Active pelvic infection
11. Intrauterine contraceptive device in place at the time of treatment
12. Current use of GnRH agonists or antagonists
13. Unstable medical conditions requiring additional monitoring during the procedure
14. Bleeding diathesis requiring medical treatment
15. Imaging suggestive of malignant disease of uterus, ovary, or cervix
16. Imaging suggestive of only adenomyosis
17. Pedunculated submucosal or subserosal myoma with a stalk less than 25% of the maximal fibroid diameter
18. Women with Medicare insurance

Method of contact/recruitment (be specific): Patients will be recruited at the time of their clinic visit, by referring physicians using a fact sheet, through advertisements on the web and on flyers posted at UCSF and in the community, and by calling patients previously interested in a study of MRgFUS.

Benefits/burden for participants (clearly identify potential for harm): The risks of participating in the study are mainly risks associated with the procedures. There is also the burden of time for participants because they complete questionnaires. There are potential benefits. Participants who undergo the MRgFUS or UAE procedures may experience a therapeutic decrease in their fibroids-related symptoms including decreased uterine bleeding, pelvic pain, or pressure, or urinary and bowel dysfunction.

Any benefits or burden to DGIM practitioners?: There is no burden to DGIM practitioners. The benefit to DGIM practitioners is the ability to provide patients will noninvasive treatment options for uterine fibroids.

Timeline for recruitment (projected start and stop dates): July 2013-July 2014

Funding source: NIH grant, subcontract with Mayo Clinic.

Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in particular): No.

Do you agree to notify us when recruitment is completed? Yes.

Date form completed: 9/20/13