



شبكة المعلومات الجامعية
التوثيق الإلكتروني والميكرو فيلم

بسم الله الرحمن الرحيم



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شبكة المعلومات الجامعية التوثيق الإلكتروني والميكروفيلم



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جامعة عين شمس

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Ulipristal Acetate Therapy versus Uterine Artery Embolization in Management of Uterine Fibroids A Randomized Controlled Trial

Thesis

*Submitted for partial fulfillment of the MD
Degree in Obstetrics and Gynecology*

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List of Abbreviations

ACOG	: American Congress of Obstetricians and Gynecologists
ALT	: Alanine transaminase
AST	: Aspartate transaminase
AUB	: Abnormal Uterine Bleeding
AUB	: Abnormal Uterine Bleeding
BMI	: Body Mass Index
EMMY	: Embolization versus hysterectoMY
ER	: Estrogen receptor
ESGE	: European Society of Gynecologic Endoscopy
FDA	: Food and Drug Administration
FIGO	: International Federation of Gynecologists and Obstetricians
FSH	: Follicle-Stimulating Hormone
GnRH	: Gonadotropin-releasing Hormone
Hgb	: Hemoglobin
HMB	: Heavy Menstrual Bleeding
ITT	: Intention to treat
LNG-IUS	: Levonorgesterel IntraUterine System
MAPK	: Mitogen-activated Protein Kinase
MRgFUS	: Magnetic Resonance imaging guided Focused Ultrasound
MRI	: Magnetic Resonance Imaging
NICE	: National Institute of Health and Care Excellence
NNH	: Number Needed to Harm
NNT	: Number Needed to Treat
OC	: Oral Contraceptive

List of Abbreviations (Cont.)

OR	: Odds Ratio
PAECs	: Progesterone-receptor modulator Associated Endometrial changes
PASS	: Power Analysis and Sample Software
PVA	: Polyvinyl Alcohol
REST	: Randomized trial of Emoblization versus Sur- gical Treatment for fibroids
RR	: Relative Risk
SERM	: Selective Estrogen Receptor Modulator
SPRM	: Selective Progesterone Receptor Modulator
TLH	: Total Laparoscopic Hysterectomy
TSH	: Thyroid Stimulating Hormone
UA	: Ulipristal Acetate
UAE	: Uterine Artery Embolization
US	: Ultrasound
VAS	: Visual Analogue Scale
WHO	: World Health Organization

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Abstract

Study objective: To prove that Ulipristal acetate is an effective line of management for uterine fibroids by causing a significant decline in fibroid volumes resulting in a substantial relief of fibroid-related symptoms, and to compare its results with those of uterine artery embolization.

Design: A randomized control trial.

Setting: Maternity Hospital, Ain Shams University and Mount Sinai Hospital, University of Toronto.

Patients: Women with symptomatic uterine fibroids.

Interventions: 70 women were randomly assigned to either Ulipristal Acetate (UA) group or uterine artery embolization (UAE) group (35 in each group). Both groups were followed up to detect the decline in fibroid size as well as the improvement of symptoms.

Measurements and Main Results: Ulipristal acetate (UA) showed a statistically significant decline in dominant fibroid volume and diameter at 3 months (37.5% and 36% respectively) and a durable effect at 6 months (34.2% and 30% respectively) compared to a 35.4% and 36% decline at 3 months and 32% and 30.7% decline in dominant fibroid volume and diameter respectively at 6 months for uterine artery embolization (UAE). Moreover, there was a statistically significant improvement in fibroid-associated symptoms among both study groups but with a higher durability at 6 months among the patients of the UA group.

Conclusion: Our study showed that a 3-month course of Ulipristal acetate (UA) is very effective in the management of symptomatic uterine fibroids and its results are comparable to uterine artery embolization (UAE), by causing a significant decline in uterine fibroid volumes resulting in the resolution of fibroid-associated symptoms. Moreover, Ulipristal acetate (UA)'s action is more durable, up to 6 months after initiating therapy.

**PROTOCOL OF A THESIS SUBMITTED FOR
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What is already known on this subject? And what does this study add?

Surgical intervention (Myomectomy or Hysterectomy) constitutes the major line of treatment for uterine fibroids, but minimally-invasive alternatives, such as Uterine artery embolization (UAE), are also available.

Uterine artery embolization (UAE) is a procedure, during which embolic material is administered into the uterine arteries to decrease the blood supply of fibroids. It has previously been shown, that uterine artery embolization (UAE) results in reduction of fibroid symptoms and improvement in the quality of life.

This study will demonstrate the efficacy of Ulipristal Acetate (UA), a selective progesterone receptor modulator (SPRM), as a medical line of treatment for fibroids.

Due to its selective anti-proliferative and pro-apoptotic action, Ulipristal Acetate (UA) is assumed to be effective in reducing abnormal uterine bleeding (AUB) and fibroid size.

1. INTRODUCTION / REVIEW

Uterine fibroids occur in 20% to 40% of women in the reproductive age, being the most common female benign tumors (**Zimmermann et al., 2012**).

Most fibroids are asymptomatic and require no treatment. However, they may lead to serious clinical symptoms, such as abnormal uterine bleeding (AUB), dysmenorrhea, chronic pelvic pain, pelvic pressure symptoms as urinary frequency or urgency and constipation (**Hirst et al., 2008**).

The mainstay of treatment of symptomatic uterine fibroids has always been surgical intervention in the form of myomectomy or hysterectomy, via various routes whether abdominal, vaginal, or laparoscopic assisted. Minimally invasive alternative treatments are also used in clinical practice, such as uterine artery embolization (**Tropeano et al., 2008**).