شبكة المعلومات الجامعية

التوثيق الإلكتروني والميكروفيلم

# بسم الله الرحمن الرحيم


HANAA ALY

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# جامعة عين شمس

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# قسم

نقسم بالله العظيم أن المادة التي تم توثيقها وتسجيلها
علي هذه الأقراص المدمجة قد أعدت دون أية تغيرات

# يجب أن

تحفظ هذه الأقراص المدمجة بعيدا عن الغبار

HANAA ALY

# Vaginal Misoprostol Prior to Intrauterine Contraceptive Device Insertion in Women Who Delivered Only By Elective Caeserean Section: Randomized Clinical Trial

Thesis

***Submitted For Partial Fulfillment of Master Degree in Obstetrics and Gynaecology***

By

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***Enas Mahmoud Mohammed Elshahid***

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# List of Abbreviations

| Abbr. | Full term |
|---|---|

AIDs..... Acquired Immune Deficiency Syndrome

AUC ..... Area Under Curve

cAMP ..... Cyclic Adenosine Mono Phosphate

CS ..... Caesarean Section

ECM……Extracellular matrix

EMB……Endometrial biopsies

HCP ..... Healthcare professionals

IUCDs..... Intrauterine contraceptive devices

LARC ..... Long acting reversible contraceptive

LNG IUS..... Levonorgestrel Intra Uterine System

MLCK ..... Myosine Light Chain Kinase

MLCP..... Myosine Light Chain phosphatase

MPA..... Misoprostolic Acid

MW ..... Molecular Weight

PGE ..... Prostaglandin E

PGF…… Prostaglandin

PIDs..... Pelvic Inflammatory Diseases

PKA ..... Protein Kinase A

RBCs..... Red Blood Cells.

STD..... Sexual transmitted diseases

Tmax..... Peak Time Concentration

VAS……..Visual Analogue Scale

WHO…….. World Health Organization

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PROTOCOL OF A THESIS FOR PARTIAL FULFILMENT OF
MASTER DEGREE IN
OBSTETRICS AND GYNEACOLOGY

# Role of vaginal misoprostol prior to IUCD insertion in women who delivered only by elective caesarean section.

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## 1.INTRODUCTION/ REVIEW

Intrauterine contraceptive devices (IUCDs) are one of the reversible effective contraceptives ***(Bahamondes et al., 2014).***

However its use is limited by the high cost in some settings and fear of pain at insertion time. For healthcare professionals (HCPs) the obstacles to its use include lack of training, fear of causing pain with the procedure and difficulties during the procedure that could end in insertion failure ***(Marions et al., 2011).***

Many HCPs believe that failure or difficulty of insertion is common in adolescents and nulligravidas and this is one of the reasons that restrict IUCD use, despite the evidence and recommendations supporting use in these groups ***(Berenson et al., 2013).***

Most IUCD insertions do not require pain control; however, a proportion of nulliparous (17%) and multiparous (11%) women experience significant pain and will require active pain management ***(Marions et al., 2011).***

Misoprostol is an inexpensive prostaglandin E1 analogue, which is associated with few side-effects ***(Wing and Gaffaney, 2006)*** and has been used extensively for its cervical softening effect before induction of labour and surgical evacuation of the uterus ***(Aronsson and Marion, 2007),*** as it reduces the force required for cervical dilatation ***(Cleary, 2010).***.

## 2.Aim of the Work

The aim of study is to evaluate the role of vaginal misoprostol (400mcg) administration 3h prior to IUCD insertion in women delivered only by elective caesarean section.

### Research hypothesis

In women who delivered by elective caesarean section undergoing IUCD insertion, vaginal misoprostol doesn't facilitate IUCD insertion.

### Research question

In women who delivered by elective caesarean section undergoing IUCD insertion, does vaginal misoprostol facilitate IUCD insertion?

**Primary outcome measures of this study are :**

1) the proportion of failed IUCD insertions regardless of the reason (e.g. immediate expulsion or impossibility to sound the uterus or any resistance or need for dilatation will be recorded) .
2) the degree of difficulty of the IUCD insertion judged as the resistance of the internal cervical os experienced by the investigator and measured by a 5-point scale, as follow:

   5 ⟹ Easy insertion.

   4 ⟹ Moderately difficult insertion.

3 ⟹ Difficult insertion.

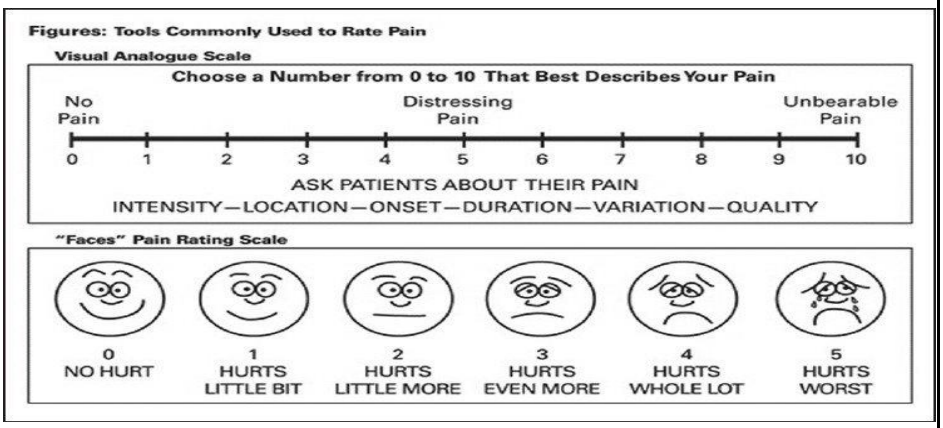
2 ⟹ Extremely difficult insertion.

1 ⟹ Failed insertion.

***(Harry and Boone, 2012)***

**Secondary outcome measures are** :

1) vasovagal-like reactions (dizziness, nausea and vomiting),
2) syncope,
3) partial- or total expulsion,
4) heavy bleeding,
5) uterine or cervical perforation,
6) pain during insertion, as estimated by the inserter.
   Pain will be measured using a 10-cm visual analog scale (VAS) graded from 0 to 10.




Visual analogue scale (VAS) for assessment of children's pain perception ***(Faezeh et al., 2013).***

**3.METHODOLOGY:**
**Patients and Methods/ Subjects and Methods/ Material and Methods**

**Study Design**: Double blinded placebo randomized controlled clinical trial.

**Place:** The study will be conducted at family planning clinic of Ain-Shams University Maternity Hospital.

**Sample size calculation:**

Using STATA program setting alpha level at 5% and power at 80% result from previous study ***(Abdella et al., 2017)*** showed that 98.6% of misoprostol group showed succefful insertion compared to 87.1% of placebo based on this we need 95 patient per group with taking in consideration on 10% drop out rate the needed sample size is 105 cases per group (210 total).

**Population of study:**

Two hundreds and ten women candidate for IUCD insertion will be enrolled in the study. Group A will receive 400 microgram of misoprostol vaginally 3 hours before IUCD insertion and group B will receive placebo.

**Inclusion Criteria:**

1. All women will be 20 to 40 years of age.
2. Desires IUCD placement and able to participate.
3. Negative pregnancy test.
4. Willing to follow- up in 6-8 weeks for a standard IUCD follow-up visit.
5. Delivered only by caesarean section.

**Exclusion Criteria:**

1. Active cervical infection.
2. Current pregnancy.