Cairo University

KASR ALAINY
CAIRO UNIVERSITY - FACULTY OF MEDICINE

"comparative study between Combined Vaginal Misoprostol withIsosorbide-5-Mononitrate versus Misoprostol Alone For Induction Of The first trimesteric Missed Abortion A Randomized Clinical Trial"

4/1/2021

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Faculty of Medicine, Cairo University Postgraduate Research Protocol Template

1. *Study*

- **Proposed Study Title:**

"comparative study between Combined Vaginal Misoprostol withIsosorbide-5-Mononitrate versus Misoprostol Alone For Induction Of The first trimesteric Missed Abortion

A Randomized Clinical Trial"

a- Degree :Master degree
b- Date of Registration of MSc April 2019

2.*Candidate*

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3. Supervisors Contact Information

Principal supervisor:

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4. Scientific committee approval

(Was it scientifically approved by the department?) Yes

Date of approval:3\8\2021

5. Background and Rationale:

Miscarriage is one of the most common complications of pregnancy. One type of abortion, missed miscarriage, occurs in 15%–20% of clinically diagnosed pregnancies and is the retention of pregnancy products in the uterus for several days or weeks after death of the fetus.**(Zhao, et al.2017)**

-
Various medical and surgical methods have been used to manage missed miscarriage. Surgical methods include dilatation and curettage, and vacuum aspiration. Because these methods are expensive and involve anesthesia, ,medical methods are generally preferred over surgical methods for abortion**(Kahnamooi,et al 2018)**

Therapeutic abortions, as well as spontaneous miscarriages, can lead to a variety of complications. Most complications are considered minor such as pain, bleeding, infection, and post-anesthesia complications, while others are major, namely uterine atony with subsequent hemorrhage, uterine perforation, injuries to adjacent organs (bladder or bowels),cervical laceration, failed abortion, septic abortion, and disseminated intravascular coagulation (DIC).**(Carlsson, et al. 2018)**

Cervical ripening means thinning, softening and opening of the cervix.Various pharmacological& non pharmacological methods are available for cervical ripening each having its own advantages& disadvantages**.(Moustafa, et al. 2019)**

Misoprostol is a synthetic prostaglandin E1 analogue which was originally developed to prevent non-steroidal anti-inflammatory drugs related gastric ulcers. However it has been used for various other indications in obstetrics and gynaecology**.(Anderson, et al. 2009)**

Nitric oxide is a potent inflammatory intercellular mediator and signaling molecule. Nitric Oxide causes relaxation of smooth muscle that induces vasodilatation of both arteries and veins causing venous pooling of the blood. It was known for its effect as an endothelium-derived relaxing factor and a primary regulator of blood pressure. Several recent studies have shown that it is involved in several aspects of female reproductive physiology, including the process of cervical ripening. Nitric oxide is less effective than prostaglandin analogues, but has fewer adverse effects **(Mousiolis, et al. 2013).**

There is an additive effect of the cervical ripening effects of nitric oxide donors and that of prostaglandins. The combination therapy allows a small dose of

nitric oxide donor to be given in combination with a small dose of prostaglandin to affect the cervical ripening. The advantage of such strategy is reducing the side effects associated with larger doses of either agent used alone**(Arteaga et al. 2005).**

6. Objectives:

The aim is to compare the therapeutic efficacy of prostaglandins when they used alone versus a combination therapy of prostaglandins and isosorbide-5-mononitrate to induce cervical ripening and effacement for induction of the first trimester missed abortion .

7. Study Design:

- Randomized Clinical Trial ■

8. Study Methods

- Population of study

All women who had first trimesteric missed abortion will be asked to participate the study

Group A (n = 30) will receive **only** vaginal Misoprostol 800mcg (4 tablets Cytotec 200mcg **)(Pfizer)**every 3 hours to a maximum of two doses or until reaching cervical ripening.
(The doses of Misoprostol will follow*the New FIGO Guidelines for Misoprostol use 2017)*

Group B (n = 30) will receive combined vaginal Misoprostol 800mcg (4 tablets Cytotec 200mcg) every 3 hours to a maximum two doses **with** Isosorbide-5-

mononitrate 20 mg (Effox20 mg)(**MINAFARM)** once at the beginning with misoprostol***(Athanasios Mousiolis et al,.2012)***

- **Study setting:**

  Embaba General Hospital Obstetrics and Gynaecology Department

- **Inclusion criteria:**
  - Maternal Age 18 - 35 years.
  - Gestational age first trimester of pregnancy (between 5-13 weeks).
  - Missed abortion confirmed by ultrasound.
  - Singleton pregnancy.
  - Normal uterus and cervix on clinical examination.
  - Cervix is not dilated.
  - No vaginal bleeding.

- **Exclusion criteria:**
  - Evidences suggesting start of spontaneous abortion and previous trial to induce abortion.
  - Presence of uterine contraction or bleeding,
  - Multi-fetal pregnancy.
  - Suspicion of septic abortion.
  - History of Previous cervical surgery or manipulation. Ex: cervical tear , cervical cauterization .
  - Uterine anomaly.
  - Presence of IUD in situ.
  - Underlying medical diseases.Ex:DM,HTN
  - History of allergy or adverse effects to vaginally administered medication e.g. isosorbide -5- mononitrate
  - Those unwilling to participate in the trial
  - Higher order cesarean section(more than three)

- **Methodology in details:**

All Patients will be informed about the study and will be included in the study after their approval and will be subjected to :

1- Consent :

Written consent will be obtained from the pregnant women who are included in the study after explanation of the study and its aims, for performing surgical evacuation for any remnants if needed .

2- Full History Taking :

- Name
- Maternal Age
- Obstetric history (Gravidity and parity)
- First day of last menstrual period
- Gestational Age
- Medical and surgical history
- Previous laparotomies and their types
- Previous Pregnancy complications
- History of smoking
- Pelvic pain

3- Clinical Examination :

- Height(in cm) and weight(in kg) measurements, BMI calculation
- Blood pressure measurement
- Bimanual Examinations (PV Examination)
- Previous scars analysis

4- Laboratory investigations :

- Preoperative and postoperative CBC
- Coagulation profile
- Kidney and liver functions
- Blood sugar level

- Investigation:

All women will undergo Trans-abdominal or Trans-Vaginal Ultra-sonography during the routine examination to confirm the inclusion criteria of the study (gestational age and confirmation of missed abortion

The patients will be allocated into 2 groups using computer-generated

randomization:

Group A (n =30) will receive **only** vaginal Misoprostol 800mcg (4 tablets Cytotec 200mcg) **)** every 3 hours to a maximum of two doses or until reaching cervical ripening or uterine contractions or bleeding assessed by the same doctor who made evaluation at the beginning.

Group B (n =30) will receive combined vaginal Misoprostol 800mcg (4 tablets Cytotec) **)** every 3 hours to a maximum of two doses or until reaching cervical ripening or start of uterine contractions or bleeding.
with Isosorbide-5-mononitrate (20 mg).
Effox 20 mg)once at the beginning with misoprostol until reaching cervical ripening or start of and uterine contractions assessed by the same doctor who made the evaluation at the beginning.

- **Intervention:**

■ **Therapeutic intervention**

☐ No intervention

- **Does the research involve?**

■ **Human participants**

☐ Biological samples/Tissues

☐ Identifiable private data/Information

- **Potential risks:**

1- Complication of nitric oxide donor : Throbbing headache, postural hypotension , nausea, vomiting, sweating, flushing.
2- Complication of prostaglandin agent: abdominal pain, diarrhea, fever, rupture uterus.

allergic reaction,chills.

- **Confidentiality of data:**
- All study-related information will be stored secured at the study site.
- All participant information will be stores in locked file cabinets in areas with limited access.
- Participants, study information will be not released outside of the study without the written permission of the participant.

9- Study outcomes

- **Primary outcomes** (Most important measurable outcomes)

Induction to abortion interval: the Duration interval between the beginning of the induction and beginning of cervical ripening assessed by cervical examination(cervix become soft and start to dilate) and uterine contractions leading to complete expulsion of the abortus spontaneous and if cervical ripening isn't occur by maximum doses the investigators will make surgical evacuation.
and also the Number of the doses of misoprostol needed to complete expulsion (spontaneous or surgical)when prostaglandins used alone and when prostaglandins and a nitric oxide donor used together .

- **Secondary outcome parameters** (other outcomes to be assessed)

Association between adverse events that increased or newly discovered when prostaglandins and a nitric oxide donor used together such as severe bleeding , headache, abdominal pain, pelvic pain, sever hypotension , backache, fever, nausea and vomiting .

10- Sample size

Sample size calculation was done using the comparison of induction to abortion interval in women with missed first trimesteric abortion treated with vaginal misoprostol combined with isosorbide mononitrate compared to those treated with misoprostol alone. As reported in previous publication (***Yehia and El ansary H 2020***.),, the mean ± SD of induction to abortion interval in combined group was approximately 10.7 ± 12.8h, while in misoprostol alone group it was approximately 20.9 ± 13.8h. Accordingly, the investigators calculated that the minimum proper sample size was 30 participants in each group to be able to reject the null

hypothesis with 80% power at $\alpha = 0.05$ level using Student's *t* test for independent samples. Sample size calculation was done using PS Power and Sample Size Calculations software, version 3.0.11 for MS Windows (William D. Dupont and Walton D., Vanderbilt University, Nashville, Tennessee, USA).

11- Statistical analysis

The collected data using patient sheet form will be coded, entered on Excel sheet and analyzed using statistical package for social sciences (SPSS) Using appropriate statistical test, with a p value less than 0.05 considered as statistically significant, P value more than 0.05 Insignificant.
A descriptive statistics will be done using frequency distribution table, graphs, means, standard deviations, median and range, or frequency and percentage.

12- Source of funding:

- Faculty of Medicine, Cairo University ☐
- Other sources: ■

  Please specify: **Self-funding**

13- Time plan:

- When to start march 2021
- When expected to finish September 2021
- When to publish?

14- References:

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Preflight Results

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Creator: Microsoft® Word 2016
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Page 5 Results

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Page 7 Results

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Page 9 Results

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Page 10 Results

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Page 12 Results

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