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Official title of the study: Coil Hysteroscopic Tubal Occlusion,
the Treatment of Hydrosalpinx Before IVF-ET

Date: 12/01/2015

Study protocol

The problem to be investigated

Project title: Coil Hysteroscopic Tubal Occlusion, the Treatment of Hydrosalpinx Before IVF-ET

Research problem: This will be an investigation to evaluate the success rate of proximal tubal occlusion with coil devices in women with hydrosalpinx and to observe the pregnancy rate with IVF-ET.

Background: Many studies have proposed that hydrosalpinx fluid may decrease the pregnancy rate following IVF-ET (Zeyneloglu HB, 1998; Strandell A, 1999; Nackley AC, 1998).

During nearly two decades, researchers have find many treatments to improve the outcomes of IVF-ET with hydrosalpinx, such as fluid extraction, salpingectomy, proximal tubal occlusion with Essure device (HTO-E) and other devices (D'Arpe S, 2015; Lorente Gonzalez J, 2016;). However, extraction cannot prevent the refluxing of fluid which may directly poison the embryos while salpingectomy may decrease the ovarian response. Laparoscopic salpingectomy may increase the risk for patients who have had a history of severe pelvic adhesions. Besides, proximal tubal occlusion with Essure have been demonstrated to be companied by some severe

complications (Walter JR, 2017). Therefore, another safer device should be investigated. Fibered platinum coils have been used in aneurysm and endovascular therapy more than a decade ago (Tsai CW, 1996). However, with wide usage, the complication was few (Syha R, 2016).

The aims: The aim of our study was to evaluate the successful and complication rate after occlusion with fibered platinum coils, and to observe the pregnancy rate following IVF-ET.

(v) The hypothesis: Hysteroscopic occlusion will be an alternative to the treatment of hydrosalpinx before IVF-ET.

2. Methods of investigation:

Subjects: 80 females between 20-45 years old with unilateral or bilateral hydrosalpinx as confirmed by HSG.

Inclusion criteria:

1. Have unilateral or bilateral hydrosalpinx as evidenced by HSG.
2. Laparoscopic surgery was considered to be contraindicated because of suspected extensive pelvic adhesions.
3. Patients are willing to undergo a hysterosalpingogram (HSG) 3 months after tubal occlusion.
4. Patients are willing to participate in this clinical study.
5. Patients are able to comprehend and give informed consent

for participation in this study.

6. Have read, understood and signed an informed consent form.

Exclusion Criteria:

Active or recent upper or lower pelvic infection

Known hypersensitivity to nickel as confirmed by skin test

Known allergy to contrast media pregnancy or suspected pregnancy

Poor general or gynecologic health

Inability or refusal to provide informed consent

Design: subjects who meet the inclusion and exclusion criteria will be eligible, all the eligible subjects will be interviewed and the purpose of the trial will be outlined. Epidemiologic data will also be collected.

Experimental procedure: hysteroscopic tubal occlusion will be performed in the 3-7days after the menses. In the third day after the surgery, a vaginal ultrasound will be performed to confirm the position of coil. 3 months later, HSG will be taken out to confirm the occlusion of tubes. After the treatment, IVF-ET will be applied and then the patients' pregnancy rate will be assessed in the following-up.