Cover Page

Official title of the study: A Randomized Clinical Trial to Assess the Efficacy of Intrauterine Balloon Compared to Intrauterine Contraceptive Device Plus Foley Catheter in the Therapy for Uterine Adhesion After Hysteroscopic Adhesiolysis.

Date: 12/01/2017

Clinical Trial Registration Number: NCT02867202

Study protocol

The problem to be investigated

Project title: A Randomized Clinical Trial to Assess the Efficacy of Intrauterine Balloon Compared to Intrauterine Contraceptive Device Plus Foley Catheter in the Therapy for Uterine Adhesion After Hysteroscopic Adhesiolysis.

Research problem: This is a RCT designed to compare the efficacy of heart-shaped intrauterine balloon and Intrauterine Contraceptive Device Plus Foley Catheter in the prevention of adhesion reformation after hysteroscopic adhesiolysis.

Background: The prevalence of IUAs varies from 0.2% in patients who undergo an intrauterine device insertion to 66.7% in patients with miscarriage curettage before. (Schenker & Margalioth, 1982) Hysteroscopic technique remain an accurate diagnosis for presence, degree of adhesions during the last two decades. (Fernandez, Al-Najjar, Chauveaud-Lambling, Frydman, & Gervaise, 2006)Hysteroscopic adhesiolysis currently become a safe and effective management to restore normal uterine cavity, however, the high incidence rate of postoperative adhesion reformation is a main challenge and difficult to solve, especially in patients with severe IUAs, in whom the recurrence rate was

reported up to 62.5%. (Yu, Wong, Cheong, Xia, & Li, 2008)Various adjunctive treatments have been proposed in an attempt to reduce postoperative recurrence. Despite the many proposed solutions, no particular method has proven to be the optima measure in preventing adhesion formation. Thereby, we put forward a new approach which combine intrauterine contraceptive device (IUD) with Foley catheter in the prevention of postoperative adhesion reformation, and there is as yet no study to confirm its value.

The aims: The aim of our study was to evaluate the efficacy of IUD plus Foley catheter and intrauterine balloon after hysteroscopic adhesiolysis in patients with moderate to severe adhesion according to the American Fertility Society (AFS) classification of intrauterine adhesions.

(v) The hypothesis: IUD plus Foley catheter presented a greater improvement in adhesion score than heart-shaped balloon in a retrospective study

2. Methods of investigation:

Subjects: The patients were totally recruited from the 1st affiliated hospital of Wenzhou Medical University between August 2016 and December 2017.

Inclusion Criteria:

1) women aged 18 to 45 years.

2) patients had no history of hysteroscopic adhesiolysis.

3) agreed to have second-look hysteroscopy.

4) moderate to severe IUA (AFS score ≥5) according to American Fertility Society (AFS) scoring system.

5) written informed consent obtained.

Exclusion Criteria:

1) minimal adhesion (AFS score <5) and

2) previous hysteroscopic adhesiolysis.

3) Inability or refusal to provide informed consent

Design: Prospective, randomized, controlled trial.

Experimental procedure: The heart-shaped intrauterine balloon is designed to fit into the cavity of the uterus, and removed on the 7th day after surgery. And hysteroscopy was taken out again after two menstrual cycles to evaluate the uterine adhesions. Intrauterine Contraceptive Device Plus Foley Catheter are inserted into the uterine after a hysteroscopic adhesiolysis. Foley Catheter is removed after three days while IUD removed at the second hysteroscopy. Uterine adhesions were judged again at the second hysteroscopy. The presence of adhesion was confirmed and uterine anatomy had been assessed at first-look and second-look hysteroscopy.