Trial Protocol

Article information: https://dx.doi.org/10.21037/tau-24-3

Scientific title: Modified herringbone position compared with traditional lithotomy position in flexible ureteroscopic lithotripsy: A multi-center prospective randomized controlled clinical study

Approved No. of ethic committee: B2021-146R
Name of the ethic committee: Ethics Committee of Zhongshan Hospital Affiliated to Fudan University
Date of approved by ethic committee: 2021.3.22

Objectives of Study:

1. Main research purposes:

(1) To compare whether there is any difference in the overall operation time between the new type of human body posture and the traditional posture;

(2) Compare the difference in stone clearance rate between the new type of human posture and the traditional posture in flexible ureteroscopic lithotripsy;

2. Secondary research purposes:

(1) To compare the difference in the comfort of the lower limbs of patients undergoing flexible ureteroscopic lithotripsy with the new type of human body position compared with the traditional position;

(2) To compare whether there is a difference in the incidence of complications after the application of the new type of human posture compared with the traditional posture in flexible ureteroscopic lithotripsy;

(3) Compare the differences in blood pressure and heart rate before and after the new type of human body position is applied to the traditional position in patients undergoing flexible ureteroscopic lithotripsy;

(4) Compare whether there is any difference in the convenience of surgeons for flexible ureteroscopic lithotripsy surgery by comparing the new type of human body position and the traditional body position;

(5) Compare whether there is a difference in the convenience of position placement of nurses in the operating room of flexible ureteroscopic lithotripsy by comparing the new type of human body position with the traditional position.

Inclusion criteria:

1. Patients diagnosed with ureteral and renal calculi;

2. Aged 18 to 75 years, in good physical condition;

3. The patient has no major organ dysfunction, and the blood routine, lung, liver, kidney and heart functions are basically normal;
4. Be able to understand the situation of this study and sign the Informed Consent.

Exclusion criteria:
1. Those who did not perform body positioning according to the method of this study;
2. The patient withdraws informed consent and requests to withdraw from the trial;
3. The investigator believes that the patient is not suitable to continue the study for some reason.

Randomization Procedure (please state who generates the random number sequence and by what method): Statisticians in the Medical Statistics Department of Zhongshan Hospital affiliated to Fudan University used statistical software to generate random sequence.

CONSORT Flowchart