

Clinical Investigation Report

Rev. : Apr.29, 2011

Product name: WEGO-PGA Suture

Product model: PGA 4-0

Sponsor: Foosin Medical Supplies Inc.,Ltd.

Center: XINQIAO HOSPITAL (THIRD MILITARY MEDICAL UNIVERSITY)

Principal Investigator (signature): Jing Li

The type of the clinical study: Clinical Validation

Apr. 29, 2011

Instructions

1. The clinical center should do the investigation according to the protocol and compile the report impartially and objectively.
2. The report should be signed by the investigator who is an experienced attending physician or has a higher title.
3. The type of the clinical study is clinical validation.

Ethics

This study complies with the Declaration of Helsinki and relevant Chinese regulations and laws. Before the start of this study, this protocol should be approved by the Ethics Committee of XINQIAO Hospital (Third Military Medical University). And every subject should be informed about the purpose, procedure, potential risks and their rights. The informed consent should be signed and documented in the study record as an appendix.

Medical Device Clinical Investigation Report

WEGO-PGA Suture can provide support for the wound during critical period of healing. It can avoid trauma to the tissue when pulled through the tissue. So the patient's suffering can be reduced. Based on requirements of <rules of medical device clinical study> (Order No.5), XINQIAO HOSPITAL (THIRD MILITARY MEDICAL UNIVERSITY) is chosen as centers for this clinical investigation. From Oct. 2010 to Apr. 2011, the clinical investigation was done to evaluate the usability and safety of the WEGO-PGA suture. "absorbable suture (Trademark: VICRYL)" of Ethicon was used as the reference. The performance of the WEGO-PGA suture was tested by the Medical Device Supervision and Test Center (Ji'nan) of China Food and Drug Administration and all the terms were qualified (Report No. Y2009041701). This investigation is approved by the Ethics Committee of XINQIAO HOSPITAL (THIRD MILITARY MEDICAL UNIVERSITY).

1. General Information

(a) Subjects

Time and site: in Hepatobiliary Surgery department from Oct. 2010 to Apr. 2011

(b) Quantity of cases

This is a non-inferiority experiment. The ratio of cases between experiment and control is 1 to 1. Based on general statistic requirement, $\alpha=0.05$, $\delta=0.1$, the average efficiency $P=0.95$, $N=12.365 \times P(1-P)/\delta^2$, the number for each group is 59. To prevent withdrawing during the investigation, 72 cases is planned to include for each group. During the study, it can be ended up when the effective cases reach 30 for both groups.

(c) Scope of subjects

(1) inclusion criteria

1. Time: a week before the start of the study

Patients: be sutured subcutaneous tissue

2. Age: 18-60 years of age (the indications of WEGO-PGA suture)

Gender: male or female

3. Patients are voluntary to sign the Informed Consent.
4. No allergies and orthostatic hypotension before the study.
5. No other medical devices are used on the patients two weeks before the starting of the study.
6. The patients can communicate with the investigator and follow all of study requirements.

(2) Exclusion criteria

1. Delirious patients
2. Patients suffering from mental illness, no self-control and/or cannot articulate themselves;
3. Patients who participated in other clinical investigations within 3 months;
4. Patients who refuse to participate in the investigation;
5. Patients who merge the heart, brain, liver, kidney, hematopoietic system and other serious primary diseases;
6. Patients suffering malnutrition or extreme physical weakness and cannot tolerate surgery;
7. Patients whose disease results in prolonging wound healing process;
8. Patients who is in poor health or ill and temporarily unsuitable for surgery during the investigation;
9. Patients who cannot follow the schedule and/or cannot cooperate with the doctors during the investigation;
10. Others who the investigator believe are not suitable for the investigation.

(3) Rejection criteria

1. Patients who meet “the exclusion criteria” after being chosen
2. Patients who breach the experiment program

3. Patients who drop out by themselves

(4) Suspension or termination of the study

1. Suspension

- a) The subject wants to withdraw.
- b) The sponsor or investigator require to suspend.

2. Termination

- a) Requirement from the Ethics Committee or the Food and Drug Administration of province or China,
- b) Adverse events appear on the subject

II . Clinical Trial Method

(a) Experimental Design

- 1. The experiment is a randomized, parallel, controlled trial design. After the screening assessment, the patients entered the experimental or control group randomly according to a random number table and were numbered. The sampling and other treatments were the same in both groups.
- 2. The investigators observed and recorded clinical data about subjects from pre-operation to post-operation. And also about the suture.
- 3. Follow-up was on the day 5-7, day 30, day 60 and day 90 after the operation. The fluctuations of time was no more than 2 days.

(b) Sign the Informed Consent

The clinical trial must follow the “Declaration of Helsinki” and Chinese clinical trials norms and regulations. Before the experiment begins, the clinical investigation must be approved by the hospital ethics committee.

Before subjects were enrolled in the experiment, investigator must explain the purpose, procedure and potential risks of the investigation to the patient or his/her designated representative. The patient

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