Clinical Investigation Protocol

Product name: WEGO-PGA suture

Product model: PGA 4-0

Sponsor: Foosin Medical Supplies Inc.,Ltd.

Center: XINQIAO HOSPITAL (THIRD MILITARY MEDICAL UNIVERSITY)

Rev.: 0910-1

Principal Investigator (signature): Jing Li

The type of the clinical study: Clinical Validation

Oct. 18, 2009

Instructions

1. The clinical investigation protocol should be established before the study.
2. The clinical investigation protocol should be designed and established by the center and the sponsor together.
3. The clinical investigation protocol, which is about Class III implanted medical device that dose not appear on market before or medical device that is manufactured based on the theory of traditional Chinese medicine, should be documented by the medical device technique review competent authorities.
4. The center and the sponsor should define the quality of cases and period for every disease in order to guarantee the experimental purpose to be reached.
5. 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.

Contact for adverse events report:

No.	Organization	Tel.
01	XINQIAO HOSPITAL (THIRD MILITARY MEDICAL UNIVERSITY)	023-68755311
02	Foosin Medical Supplies Inc.,Ltd.	0631-5716087
China Food and Drug Administration (CFDA): 010-68313344-1013		

(Serious adverse events should be reported to above organizations within 24 hours!)

Clinical Investigation Protocol of WEGO-PGA Suture

I. Background of the clinical study

WEGO-PGA Suture are synthetic, absorbable sterile surgical sutures composed of Polyglycolic Acid (PGA). It has good biocompatibility, minimum tissue reaction, high strength, proper elasticity and pliability, no toxicity, no irritation and predictable degradation and absorption period. The material can be absorbed after hydrolysis. It can be used in obstetrics and gynecology, general surgery, orthopedics, urology, pediatrics, dentistry, ENT, ophthalmology, hepatobiliary surgery and orthopedics.

Performance of WEGO-PGA Suture was tested by medical device supervision and test center (Ji'nan) of China Food and Drug Administration and all results are qualified (Report No. Y2009041701). XINQIAO HOSPITAL (THIRD MILITARY MEDICAL UNIVERSITY) is assigned as one of the clinical investigation centers to evaluate the effectiveness and safety of WEGO-PGA Suture.

II. The mechanism and features; study coverage

Mechanism: WEGO-PGA Suture consists of the needle and the suture. The suture is synthetic and absorbable, which is made of Polyglycolic Acid - $(C_2O_2H_2)_n$. It will lose its strength along with hydrolysis. The degradation products (ethylene glycol, and polylactic acid) will be absorbed.

Features: WEGO-PGA Suture elicits a minimal initial inflammatory reaction in tissues; has predicable strength and absorption period; is soft, smooth and easy to tie; no residues after absorption.

All performances comply with product standard and other relevant industry standards. The device is sterile and 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.

Coverage: soft tissue approximation (not include cardiovascular and neurological tissue)

III. Indications or functions:

WEGO-PGA Suture is intended for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery. The safety and effectiveness of WEGO-PGA Suture in cardiovascular tissue and neurological tissue have not been established.

IV. Contents and purpose of the clinical investigation:

(A) Purpose:

"absorbable suture (Trademark: VICRYL)" of Ethicon is used as the control. The study is to evaluate the safety and effectiveness of WEGO-PGA suture made by FOOSIN MEDICAL SUPPLIES INC., LTD.

(B) Evaluation items

1. Effectiveness and usability

a) Is the package intact?

b) Is the connection between every part of the product firm?

c) Is the suture easy to pull through the tissue?

d) Are the knots easy to loose?

2. Safety:

a) Is the needle broken during the operation?

b) Is the strength of the suture enough? Is it easy to broken?

c) Are there any adverse reactions? Are they related to the needle and suture?

Type of the adverse reactions	The relationship with the product	Severity of the adverse reactions	Follow-up outcome
Toxic reactions	1( ) 2( ) 3 ( ) 4 ( ) 5 ( )	1( ) 2( ) 3 ( ) 4 ( )	
Allergies	1( ) 2( ) 3 ( ) 4 ( ) 5 ( )	1( ) 2( ) 3 ( ) 4 ( )	
Liver and kidney dysfunction	1( ) 2( ) 3 ( ) 4 ( ) 5 ( )	1( ) 2( ) 3 ( ) 4 ( )	
Blood system damage	1( ) 2( ) 3 ( ) 4 ( ) 5 ( )	1( ) 2( ) 3 ( ) 4 ( )	
Exudation	1( ) 2( ) 3 ( ) 4 ( ) 5 ( )	1( ) 2( ) 3 ( ) 4 ( )	
Swelling	1( ) 2( ) 3 ( ) 4 ( ) 5 ( )	1( ) 2( ) 3 ( ) 4 ( )	
The temperature of skin rises	1( ) 2( ) 3 ( ) 4 ( ) 5 ( )	1( ) 2( ) 3 ( ) 4 ( )	

Subcutaneous fat liquefaction	1( ) 2( ) 3 ( ) 4 ( ) 5 ( )	1( ) 2( ) 3 ( ) 4 ( )	
Wound infection	1( ) 2( ) 3 ( ) 4 ( ) 5 ( )	1( ) 2( ) 3 ( ) 4 ( )	
Wound dehiscence	1( ) 2( ) 3 ( ) 4 ( ) 5 ( )	1( ) 2( ) 3 ( ) 4 ( )	

V. General design

（A）Choose the centers

According to the list of "National Drug clinical study centers" designated by the China Food and Drug Administration, centers for this study are chosen. Based on requirements of <rules of medical device clinical study> (Order No.5), XINQIAO HOSPITAL (THIRD MILITARY MEDICAL UNIVERSITY) and Southwest HOSPITAL, THIRD MILITARY MEDICAL UNIVERSITY are chosen as centers for this clinical investigation.

（B）Methods:

1. The investigation uses two centers, random and parallel control design. All the subjects who meet the inclusion criteria enter the control or experimental group according to the random table successively. Sampling and other operational aspects in the control and experimental group should be same.

2. Before the study, during and after the operation, the investigator should check and record the condition of subjects and the sutures.

3. Follow-up visits will be carried out on 5-7th days, 30th days, 60th days, and 90th days after surgery. Fluctuations of time is no more than 2 days.

(C) Informed Consent

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 or his/her representative should be fully informed about the purpose, procedure and potential risks in written form. The subjects should be told that they have the right to withdraw from this investigation at any time. Before involved in this investigation, every subject should be provided a written Informed Consent (as an appendix included in the protocol). The investigator gets the Informed Consent and keeps it in the document before every subject enters this investigation.

(D) Informed Consent

Investigation device:

Product Name: WEGO-PGA suture

Manufacture: FOOSIN MEDICAL SUPPLIES INC., Ltd.

Specification: PGA 4-0

Lot. : 20090811

Validity: 3 years

Control devices:

Product Name: “absorbable suture (Trademark: VICRYL)”

Manufacture: Ethicon Inc.

Specification: J397

Lot. : BJ2148

Validity: 3 years

(E) Use

The device will be used according to standard clinical procedure in operating room.

(F) Clinical Observation

Before the start of the study, subjects should take physical examination; during the study, investigator should observe and record subjects’ symptoms and the situation of surgical site.

During the investigation, the censor designated by Foosin should visit and inspect the center regularly. It would guarantee that everything is compliant with the clinical study protocol and the clinical data is filled according to relevant requirements. All the investigators, who participate in the clinical investigation, should take unified training and use unified method to record data according to the same standards.

Investigators should fill out the CRF according to its requirements. All contents in the CRF should be recorded truthfully, detailedly and seriously. The results should be verified in order to guarantee the reliability of data. All conclusion should base on raw data. There should be corresponding data management measure during both clinical experiment and data processing stage.

(G) Record

Investigators should fill out all study data, including validation of all subjects (checking different records effectively, such as CRF and hospital raw data), all signed Informed Consents and CRFs. They are responsible for the summary of the clinical investigation.

(H) Possibility analysis of success and failure

This clinical investigation will be done in XINQIAO Hospital (Third Military Medical University) , which is one of centers approved by CFDA. WEGO-PGA suture complies with the product standard of Foosin, and proves to be qualified after testing by medical device supervision and test center (Jinan) of China Food and Drug Administration. The clinical expectation of WEGO-PGA suture is safe and the success possibility is large.

1. Potential risks

(1) Bio burden/other contamination

Bio burden is the accumulation of bacterial and exists on the parts of unsterile device. If the manufacturer can produce and transport according to industry standards, risks will reduce. Risks are reduced by testing the bio burden of new parts or purchasing those parts from suppliers who have established a quality management system. Other contaminations come from produce operation, environment, product delivery, etc.

Pyrogenic reaction: Endotoxin exists in the cell wall of all Gram-negative microorganism, which has LPS. It will cause pyrogenic reaction in warm blood animal body. This risk depends on the neatness of produce environment.

Invalid sterilization will results in bacteria on the device.

(2) Biocompatibility

Biological incompatibility means that device and human body cannot adapt to each other. The risk is the result of the body's rejection and will lead to exuding (around the wound), swelling and rising of skin temperature.

(3) Broken needle

This risk is due to bad elasticity and pliability of the needle. If the needle breaks, it will prevent the operation.

(4) The suture is hydrolyzed and absorbed too early

If the water content is higher than the prescribed value, the suture will be hydrolyzed and absorbed by human body. The strength will reduce and wound will split.

(5) The connection between the needle and the suture is not firm enough. If the needle breaks, it

will prevent the operation.

(6) The suture material has antigenicity or the surface is rough. It may lead to poisoning, allergies, liver and kidney dysfunction, blood system damage, exuding around the wound, swelling and rising of skin temperature.

Although subjects have taken medical examination before the start of the investigation, there may be following risks:

a) Surgical site infection or infection deterioration

b) Re-suture due to product performance

c) Poisoning, rejection and allergies

d) Liver and kidney dysfunction

e) Blood system damage

f) Exuding around the wound

g) Subcutaneous fat liquefaction

The incidence of these risks is low, but they appeared on similar devices in the past. If they appear, investigators will deal with them according to appropriate protocols. The use of protocol should base on real condition and the principle of minimum injury.

2. Measures to reduce risks

(1) The quality of product used in this investigation must be tested and validated

(2) To screen subjects according to the inclusion and exclusion criteria.

(3) Operation regulations should be complied with strictly.

(4) The subject's condition should be supervised closely in order to guarantee the subject's safety in the maximum extent possible

VI. Evaluation criteria

The success criteria are:

a) The equivalence between experiment and control group can be proved

b) There are no serious quality problems on the device during this investigation.

c) There are no serious adverse reactions or adverse events related to the device.

VII. The period of the clinical investigation:

After the clinical contract is sign by both the sponsor and centers, personnel will receive relevant training. CRF will be printed according to the evaluation standard in this investigation.