

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 02/27/2016

ClinicalTrials.gov ID: NCT02694081

Study Identification

Unique Protocol ID: 130021

Brief Title: The Advantages and Disadvantages Between Uncut Roux-en-Y Reconstruction and Billroth II Reconstruction After Laparoscopy-assisted Distal Gastrectomy for Gastric

Official Title: The Advantages and Disadvantages Between Uncut Roux-en-Y Reconstruction

Secondary IDs: 714488468 [Department of Gastrointestinal and Anal Surgery]

Study Status

Record Verification: February 2016

Overall Status: Not yet recruiting

Study Start: February 2016

Primary Completion: February 2017 [Anticipated]

Study Completion: February 2017 [Anticipated]

Sponsor/Collaborators

Sponsor: Jilin University

Responsible Party: Principal Investigator

Investigator: Xiaodi Yang [xyang]

Official Title: Assisted Investigator

Affiliation: Jilin University

Collaborators:

Oversight

FDA Regulated?: No

IND/IDE Protocol?: No

Review Board: Approval Status: Pending

Board Name: the First Hospital Ethics Committee of Jilin University

Board Affiliation: The First Hospital of Jilin University:China

Phone: 0431-81875617

Email: wangquan-jlcc@hotmail.com

Data Monitoring?: Yes

Plan to Share Data?:

Oversight Authorities: China: Ministry of Health

Study Description

Brief Summary: The Advantages and Disadvantages Between Uncut Roux-en-Y Reconstruction and Billroth II Reconstruction After Laparoscopy-assisted Distal Gastrectomy for Gastric.

Detailed Description: To search which is the better reconstructions by comparing and analyzing the advantages and disadvantages between Uncut Roux-en-Y and Billroth II reconstructions after laparoscopy-assisted distal gastrectomy for gastric cancer.

Method: It's a prospective study including all patients underwent laparoscopy-assisted distal gastrectomy (LADG) in the First Hospital of Jilin University, from February 2016 to February 2017. All surgical procedures will be performed by the single surgery team, which is leaded by professor Wang Quan. The reconstruction method will be selected randomly from Uncut Roux-en-Y and Billroth II anastomosis by drawing lots preoperatively without distinct indications. Clinical data, operation data and perioperative complications and related physiological indexes of differences.

Conditions

Conditions: Gastric Cancer

Keywords: reflux
residue
Gastric stasis
Emptying time

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Intervention Model: Parallel Assignment

Number of Arms: 2

Masking: Single Blind (Subject)

Allocation: Randomized

Endpoint Classification: Safety/Efficacy Study

Enrollment: 100 [Anticipated]

Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Experimental: Uncut Roux-en-Y Reconstruction Uncut Roux-en-Y Reconstruction will be used after laparoscopy-assisted distal gastrectomy for early gastric cancer. | Procedure/Surgery: Uncut Roux-en-Y Reconstruction All surgical procedures will be performed by the single surgery team ,which is leaded by professor Wang Quan. Uncut Roux-en-Y construction will be used in this group. |
| Active Comparator: Billroth II Reconstruction Billroth II Reconstruction will be used after laparoscopy-assisted distal gastrectomy for early gastric cancer. | Procedure/Surgery: Billroth II Reconstruction All surgical procedures will be performed by the single surgery team ,which is leaded by professor Wang Quan. Uncut Roux-en-Y construction will be used in this group. |

Outcome Measures

Primary Outcome Measure:

1. The time of reconstruction during operations of Uncut Roux-en-Y Reconstruction and Billroth II Reconstruction
[Time Frame: within 2 hours after surgery] [Safety Issue: Yes]
The time of reconstruction operation will be recorded in the operating note by nurses in minutes.
2. change of potential of hydrogen (pH) in remnant stomach
[Time Frame: 1-6 days after surgery] [Safety Issue: Yes]
In the morning of 1-6 days after operation , monitor the number of gastric juice's potential of hydrogen (pH) value through gastric tube and write down the data. So if the data is greater than 7,the complication of bile reflux happened
3. the amount of blood loss during operations of Uncut Roux-en-Y Reconstruction and Billroth II Reconstruction
[Time Frame: within 2 hours after surgery] [Safety Issue: Yes]
During the operation the amount of blood loss will be recorded in the operating note by nurses in milliliters.

Secondary Outcome Measure:

4. the number of patients with the complication of Residual food
[Time Frame: 6 month after surgery] [Safety Issue: Yes]
During the upper gastrointestinal radiography , if there is residual food,the meglumine diatrizoate will be separate and then write down the number.
5. the number of patients with the complication of Reflux esophagitis
[Time Frame: 6 month after surgery] [Safety Issue: Yes]
During the upper gastrointestinal radiography,if there is meglumine diatrizoate refluxing to esophagus,it will be observed and written down in number.

Other Pre-specified Outcome Measures:

6. the number of patients with the complication of gastroesophageal reflux disease(GERD)
[Time Frame: 6 month after surgery] [Safety Issue: Yes]
all patients of this clinical trial will be investigated by Gastroesophageal reflux disease questionnaire(GerdQ),and all patients whose score is beyond 8 will be collected.

Eligibility

Minimum Age:

Maximum Age: 85 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Clinical diagnosis of distal gastric cancer
- underwent laparoscopy-assisted distal gastrectomy

Exclusion Criteria:

- have simultaneously other cancer
- have severe systemic inflammatory disease ,serious illness such as diabetes, chronic lung diseases
- have upper gastrointestinal surgery
- can't bear the gastric tube
- the period is too late or the tumor is too large to carry on a laparoscopy assisted radical distal gastrectomy

Contacts/Locations

Central Contact: Dong Yang, postgraduate
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Central Contact Backup:

Study Officials: Quan Wang, professor
Study Director
the First Hospital of Jilin University

Locations:

References

Citations:

Links:

Study Data/Documents:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services