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Fast Track Surgery With Laparoscopic-assisted Gastrectomy for Advanced Gastric Cancer: a Randomized Controlled Trial (FTSlapAG)

This study has been completed.

Sponsor:

Quan Wang

Information provided by (Responsible Party):

Quan Wang, First Hospital of Jilin University

ClinicalTrials.gov Identifier:

NCT01955096

First received: September 25, 2013

Last updated: October 8, 2013

Last verified: October 2013

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Tracking Information	
First Received Date ICMJE	September 25, 2013
Last Updated Date	October 8, 2013
Start Date ICMJE	September 2010
Primary Completion Date	September 2012 (final data collection date for primary outcome measure)
Current Primary Outcome Measures ICMJE (submitted: September 29, 2013)	<ul style="list-style-type: none"> Ambulation time [Time Frame: within the first 30 days (plus or minus 3 days) after surgery] [Designated as safety issue: Yes] defecation time [Time Frame: within the first 30 days (plus or minus 3 days) after surgery] [Designated as safety issue: Yes] food intake time [Time Frame: within the first 30 days (plus or minus 3 days) after surgery] [Designated as safety issue: Yes]
Original Primary Outcome Measures ICMJE	Same as current
Change History	Complete list of historical versions of study NCT01955096 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE (submitted: September 29, 2013)	<ul style="list-style-type: none"> Complications [Time Frame: one year] [Designated as safety issue: Yes] readmission [Time Frame: one year] [Designated as safety issue: Yes]
Original Secondary Outcome Measures ICMJE	Same as current
Current Other Outcome Measures ICMJE	Not Provided
Original Other Outcome Measures ICMJE	Not Provided
Descriptive Information	
Brief Title ICMJE	Fast Track Surgery With Laparoscopic-assisted Gastrectomy for Advanced Gastric Cancer: a Randomized Controlled Trial
Official Title ICMJE	Fast Track Surgery With Laparoscopic-assisted Gastrectomy for Advanced Gastric
Brief Summary	The purpose of this study is to to investigate the feasibility and safety of fast-track surgery when combined with laparoscopic-assisted gastrectomy for advanced gastric cancer patients.
Detailed Description	Methods: We designed a prospective randomized, controlled clinical trial then recruited 61 consecutive

	advanced gastric cancer patients. (Trial registration number: JLUFHC1722013) Further divide into a fast-track surgery group (n=30) and a conventional surgery group (n=31). Surgical technique in both groups is same laparoscopic-assisted gastrectomy with D2 lymphadenectomy. Compare outcomes includes length of hospital stay, return to normal diet and postoperative complications. Results: Recovery parameters such as the length of time to return to normal diet; to the first defecation; start of ambulation time ;the mean hospital stay will be all less in patients assigned to the fast track surgery protocol compared with those in the conventional care programme. Conclusion: We will consider fast-track rehabilitation to be safe and feasible in advanced gastric cancer patients. Moreover, it will result in decreased hospital stay.
Study Type <small>ICMJE</small>	Interventional
Study Phase	<i>Not Provided</i>
Study Design <small>ICMJE</small>	Allocation: Randomized Endpoint Classification: Safety/Efficacy Study Intervention Model: Parallel Assignment Masking: Single Blind (Subject) Primary Purpose: Supportive Care
Condition <small>ICMJE</small>	Gastric Cancer
Intervention <small>ICMJE</small>	<ul style="list-style-type: none"> • Procedure: fast-track surgery The included patients will be randomly divided to two groups :30 that will undergo LAG with FTS rehabilitation programme and 31 that also will undergo LAG but receive conventional postoperative care.Laparoscopy-assisted gastrectomy will be carried out in this approach.There will be no difference in the surgical procedures of both groups.The criteria for discharge are: tolerance of solid diet, return of bowel habits and ability to walk on their own. • Procedure: conventional postoperative care The included patients will be randomly divided to two groups :30 that will undergo LAG with FTS rehabilitation programme and 31 that also will undergo LAG but receive conventional postoperative care.Laparoscopy-assisted gastrectomy will be carried out in this approach.There will be no difference in the surgical procedures of both groups.The criteria for discharge are: tolerance of solid diet, return of bowel habits and ability to walk on their own.
Study Arm (s)	<ul style="list-style-type: none"> • Experimental: fast-track surgery The included patients will be randomly divided to two groups :30 that will undergo LAG with FTS rehabilitation programme and 31 that also will undergo LAG but receive conventional postoperative care.Laparoscopy-assisted gastrectomy will be carried out in this approach.There will be no difference in the surgical procedures of both groups.The criteria for discharge are: tolerance of solid diet, return of bowel habits and ability to walk on their own. Intervention: Procedure: fast-track surgery • conventional postoperative care The included patients will be randomly divided to two groups :30 that will undergo LAG with FTS rehabilitation programme and 31 that also will undergo LAG but receive conventional postoperative care.Laparoscopy-assisted gastrectomy will be carried out in this approach.There will be no difference in the surgical procedures of both groups.The criteria for discharge are: tolerance of solid diet, return of bowel habits and ability to walk on their own. Intervention: Procedure: conventional postoperative care
Publications *	<i>Not Provided</i>
<p>* Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.</p>	
Recruitment Information	
Recruitment Status <small>ICMJE</small>	Completed
Enrollment <small>ICMJE</small>	61
Completion Date	October 2012
Primary Completion Date	September 2012 (final data collection date for primary outcome measure)
Eligibility Criteria <small>ICMJE</small>	<p>Inclusion Criteria:</p> <ul style="list-style-type: none"> • Diagnosis of advanced gastric cancer, elective laparoscopic surgery and age under 75. <p>Exclusion Criteria:</p> <ul style="list-style-type: none"> • Patients with early gastric cancer, received neoadjuvant chemotherapy, had pyloric obstruction or with

	distant metastasis were excluded from the study.
Gender	Both
Ages	up to 75 Years
Accepts Healthy Volunteers	No
Contacts <small>ICMJE</small>	Contact information is only displayed when the study is recruiting subjects
Listed Location Countries <small>ICMJE</small>	Not Provided
Removed Location Countries	
Administrative Information	
NCT Number <small>ICMJE</small>	NCT01955096
Other Study ID Numbers <small>ICMJE</small>	2013-172, 2013-172
Has Data Monitoring Committee	Yes
Responsible Party	Quan Wang, First Hospital of Jilin University
Study Sponsor <small>ICMJE</small>	Quan Wang
Collaborators <small>ICMJE</small>	Not Provided
Investigators <small>ICMJE</small>	Not Provided
Information Provided By	First Hospital of Jilin University
Verification Date	October 2013
<small>ICMJE</small> Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP	