

Trial record **1 of 1** for: NCT01955096[Previous Study](#) | [Return to List](#) | [Next Study](#)**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

[History of Changes](#)[Full Text View](#)[Tabular View](#)[No Study Results Posted](#)[Disclaimer](#)[How to Read a Study Record](#)**Tracking Information**

<b>First Received Date</b> <a href="#">ICMJE</a>	September 25, 2013
<b>Last Updated Date</b>	October 8, 2013
<b>Start Date</b> <a href="#">ICMJE</a>	September 2010
<b>Primary Completion Date</b>	September 2012 (final data collection date for primary outcome measure)
<b>Current Primary Outcome Measures</b> <a href="#">ICMJE</a> (submitted: September 29, 2013)	<ul style="list-style-type: none"><li>Ambulation time [ Time Frame: within the first 30 days (plus or minus 3 days) after surgery ] [ Designated as safety issue: Yes ]</li><li>defection time [ Time Frame: within the first 30 days (plus or minus 3 days) after surgery ] [ Designated as safety issue: Yes ]</li><li>food intake time [ Time Frame: within the first 30 days (plus or minus 3 days) after surgery ] [ Designated as safety issue: Yes ]</li></ul>
<b>Original Primary Outcome Measures</b> <a href="#">ICMJE</a>	<i>Same as current</i>
<b>Change History</b>	<a href="#">Complete list of historical versions of study NCT01955096 on ClinicalTrials.gov Archive Site</a>
<b>Current Secondary Outcome Measures</b> <a href="#">ICMJE</a> (submitted: September 29, 2013)	<ul style="list-style-type: none"><li>Complications [ Time Frame: one year ] [ Designated as safety issue: Yes ]</li><li>readmission [ Time Frame: one year ] [ Designated as safety issue: Yes ]</li></ul>
<b>Original Secondary Outcome Measures</b> <a href="#">ICMJE</a>	<i>Same as current</i>
<b>Current Other Outcome Measures</b> <a href="#">ICMJE</a>	<i>Not Provided</i>
<b>Original Other Outcome Measures</b> <a href="#">ICMJE</a>	<i>Not Provided</i>

**Descriptive Information**

<b>Brief Title</b> <a href="#">ICMJE</a>	Fast Track Surgery With Laparoscopic-assisted Gastrectomy for Advanced Gastric Cancer: a Randomized Controlled Trial
<b>Official Title</b> <a href="#">ICMJE</a>	Fast Track Surgery With Laparoscopic-assisted Gastrectomy for Advanced Gastric
<b>Brief Summary</b>	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.
<b>Detailed Description</b>	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.
<b>Study Type</b> <a href="#">ICMJE</a>	Interventional
<b>Study Phase</b>	<i>Not Provided</i>
<b>Study Design</b> <a href="#">ICMJE</a>	Allocation: Randomized Endpoint Classification: Safety/Efficacy Study Intervention Model: Parallel Assignment Masking: Single Blind (Subject) Primary Purpose: Supportive Care
<b>Condition</b> <a href="#">ICMJE</a>	Gastric Cancer
<b>Intervention</b> <a href="#">ICMJE</a>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> </ul>
<b>Study Arm (s)</b>	<ul style="list-style-type: none"> <li>• 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</li> <li>• 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</li> </ul>
<b>Publications *</b>	<i>Not Provided</i>
* Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.	
<b>Recruitment Information</b>	
<b>Recruitment Status</b> <a href="#">ICMJE</a>	Completed
<b>Enrollment</b> <a href="#">ICMJE</a>	61
<b>Completion Date</b>	October 2012
<b>Primary Completion Date</b>	September 2012 (final data collection date for primary outcome measure)
<b>Eligibility Criteria</b> <a href="#">ICMJE</a>	<p>Inclusion Criteria:</p> <ul style="list-style-type: none"> <li>• Diagnosis of advanced gastric cancer, elective laparoscopic surgery and age under 75.</li> </ul> <p>Exclusion Criteria:</p> <ul style="list-style-type: none"> <li>• Patients with early gastric cancer, received neoadjuvant chemotherapy, had pyloric obstruction or with</li> </ul>

	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 <a href="#">International Committee of Medical Journal Editors</a> and the <a href="#">World Health Organization ICTRP</a>	