

Status : **Approved**

First submit date : 2014/09/08

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1. Background

CRIS Registration Number	KCT0001237
Unique Protocol ID	2013-04-018
Public/Brief Title	Safety and Efficacy of transformable patient positioning device(EZ-FIX) for endoscopic retrograde cholangiopancreatography under intravenous sedation: a prospective, randomized trial
Scientific Title	Safety and Efficacy of transformable patient positioning device(EZ-FIX) for endoscopic retrograde cholangiopancreatography under intravenous sedation: a prospective, randomized trial
Acronym	
Investigate	No
IND/IDE Protocol	No
Registered at Other Registry	No
Name of Registry / Registration number	

2. Institutional Review Board

Board Approval Status	Submitted approval ;
Board Approval Number	CBNUH 2013-04-018-002
Approval Date	2013-06-26
Board Name	Chungbuk National University Hospital Institutional Review Board
Data Monitoring Committee	No

3. Contact Details

Contact Person for Principal Investigator / Scientific Queries	
Name	Joung-Ho Han
Degree	assistant professor
- Institute	Chungbuk National University Hospital
Contact Person for Public Queries	
Name	Joung-Ho Han
Degree	assistant professor
Institute	Chungbuk National University Hospital
Contact Person for Updating Information	
Name	Joung-Ho Han
Degree	assistant professor
Institute	Chungbuk National University Hospital

4. Status

Study Center	Single
Overall Recruitment Status	Completed
Date of First Enrollment	2013-06-20
State of First Enrollment	Actual
Target Sample Size	92
Primary Completion Date (Primary Complete date)	2014-06-02
Study Completion Date (Study Complete Date)	2014-09-14
Participating Recruitment Status 1	
Institute Name	Chungbuk National University Hospital
Recruitment Status	Completed
Date of First Enrollment	2013-06-20
State of First Enrollment	Actual

5. Source of Monetary / Material Support

Source of Monetary/Material Support 1	
Organization Name	Chungbuk National University Hospital
Organization Type	Medical Institute
Project ID	2013-04-018

6. Sponsor Organization

Sponsor Organization 1	
Institute Name	Chungbuk National University Hospital
Institute Type	Medical Institute

7. Study Summary

Lay Summary	<p>Background : Endoscopic retrograde cholangiopancreatography (ERCP) is a kind of high-risk procedure and frequently performed under deep sedation for the accuracy of the procedure and safety of patient. EZ-FIX is a patient positioning device with using tiny polyethylene particles and compressed air, is expected to contribute sedation safety by fixing the patient in transient failure of maintenance of sedation that can occur during ERCP procedure. However, no studies have yet about the efficacy and safety of EZ-FIX in therapeutic ERCP.</p> <p>Aim : This prospective, randomized study was planned to compare the efficacy and safety of EZ-FIX® with control group in therapeutic ERCP.</p> <p>Methods : This study compared using EX-FIX group(n=46) to non-EZ-FIX group(n=46). Midazolam and propofol titrated to a moderate level of sedation during therapeutic ERCP, was performed by trained registered nurses under endoscopist supervision. Primary outcome measurements were incidence of hypoxia, mean dose of propofol and recovery time. Secondary outcome measurements included sedation satisfaction of endoscopist, assisted nurse, and patients.</p>
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8. Study Design

Study Type	Interventional Study	
Primary Purpose	Supportive Care	
Phase	Phase4	
Intervention Model	Parallel	
Blinding/Masking	Open	
Allocation	RCT	
Intervention Type	Device	
Intervention Description	<p>ERCP is a kind of high-risk procedure and frequently performed under deep sedation for the accuracy of the procedure and safety of patient. EZ-FIX is a patient positioning device with using tiny polyethylene particles and compressed air, is expected to contribute sedation safety by fixing the patient in transient failure of maintenance of sedation that can occur during ERCP procedure. However, no studies have yet about the efficacy and safety of EZ-FIX in therapeutic ERCP.</p> <p>This prospective, randomized study was planned to compare the efficacy and safety of EZ-FIX® with control group in therapeutic ERCP.</p>	
Number of Arms	2	
Arm 1	Arm Label	EZ-FIX group
	Target Sample Size	46
	Arm Type	experimental
	Arm Description	During ERCP, this group will be fixed with EZ-FIX.
Arm 2	Arm Label	Classic group
	Target Sample Size	46
	Arm Type	no intervention
	Arm Description	During ERCP, this group will not be fixed with EZ-FIX. This method is conventional.

9. Subject Eligibility

Condition(s) / Problem(s)	* Diseases of the digestive system 치료목적의 ERCP를 받는 환자	
Rare Disease	No	
Inclusion Criteria	Gender	Both
	Age	18 Year ~ N/A No Limit
	Description	The patient older than 18 years need the therapeutic ERCP over 15 minutes.
Exclusion Criteria	outpatients, pregnancy, allergy to midazolam or propofol, people experienced complication during sedative endoscopy, alcohol abuser, history of neuromuscular disease, acute or chronic pulmonary disease, sleep apnea, American Society of Anesthesiologists (ASA) class V, mental retardation, not agreed with informed consent.	
Accepting Healthy Volunteers	No	

10. Outcome Measure(s)

Type of Primary Outcome	/Safety/Efficacy
Primary Outcome 1	
Outcome	dose of propofol
Timepoint	After procedure
Primary Outcome 2	
Outcome	incidence of hypoxia, hypotension
Timepoint	After procedure
Secondary Outcome 1	
Outcome	recovery time
Timepoint	After procedure
Secondary Outcome 2	
Outcome	satisfaction degree of doctor and nurse
Timepoint	After procedure

11. Publication

Number of publications	0
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