

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: August 16, 2021

ClinicalTrials.gov ID: NCT04639323

Study Identification

Unique Protocol ID: CHESS2005
Brief Title: Endoscopic Ruler for the Assessment of Variceal Bleeding Risks (CHESS2005)
Official Title: Endoscopic Ruler for the Assessment of Variceal Bleeding Risks in Portal Hypertension (CHESS2005): A Prospective Multicenter Trial
Secondary IDs:

Study Status

Record Verification: August 2021
Overall Status: Recruiting
Study Start: December 23, 2020 [Actual]
Primary Completion: November 13, 2021 [Anticipated]
Study Completion: November 13, 2022 [Anticipated]

Sponsor/Collaborators

Sponsor: Hepatopancreatobiliary Surgery Institute of Gansu Province
Responsible Party: Principal Investigator
Investigator: Xiaolong Qi [xlqi]
Official Title: Director, Institute of Portal Hypertension
Affiliation: Hepatopancreatobiliary Surgery Institute of Gansu Province
Collaborators: LanZhou University
Tianjin Second People's Hospital
The First Affiliated Hospital with Nanjing Medical University
People's Hospital of Ningxia Hui Autonomous Region
The Second Affiliated Hospital of Baotou Medical College
The Third Xiangya Hospital of Central South University
The Second Hospital of Hebei Medical University
The Affiliated Hospital Of Southwest Medical University
First Hospital of China Medical University

Oversight

U.S. FDA-regulated Drug: No
U.S. FDA-regulated Device: No
U.S. FDA IND/IDE: No
Human Subjects Review: Board Status: Approved

Approval Number: 2020-LL-019
Board Name: Ethics committee
Board Affiliation: People's Hospital of Ningxia Hui Autonomous Region
Phone:
Email:
Address:

301 Zhengyuan North Street, Jinfeng District, Yinchuan, Ningxia

Data Monitoring: Yes
FDA Regulated Intervention: No

Study Description

Brief Summary: The presence of varices is a serious complication of portal hypertension in liver disease. To prevent variceal haemorrhage, screening and surveillance aims to detect high-risk varices related to varices size and determine the need for primary prophylaxis. Varices size evaluated by endoscopists might not be perfect reference, influenced by experience and machine. Endoscopic ruler is a novel tool to measure the varices size under the endoscopy. The investigators aim to evaluate the bias of varices size between endoscopists and endoscopic ruler as the reference.

Detailed Description:

Conditions

Conditions: Liver Cirrhosis
Portal Hypertension
Gastroesophageal Varices
Keywords: Esophagogastroduodenoscopy
Endoscopic ruler
Varices size

Study Design

Study Type: Observational [Patient Registry]
Observational Study Model: Cohort
Time Perspective: Prospective
Biospecimen Retention:
Biospecimen Description:
Enrollment: 266 [Anticipated]
Number of Groups/Cohorts: 1
Target Follow-Up Duration: 7 Days

Groups and Interventions

Groups/Cohorts	Interventions
Overall eligible participants Eligible participants whose varix size will be measured by endoscopists and endoscopic ruler will receive standard esophagogastroduodenoscopy	Diagnostic Test: Endoscopic ruler Endoscopic ruler for varices in portal hypertension Product uses: measuring the diameter of the

Groups/Cohorts	Interventions
	veins under the endoscopy for the assessment of the risk of variceal haemorrhage in patients with portal hypertension Black and white measuring rule is highly recognizable under the endoscopy The width of each cell is 1 mm, and the measuring range is 0-10 mm With smooth edge, safe and reliable

Outcome Measures

- Primary Outcome Measure:
- 1. The intraclass correlation coefficient (ICC) of the varix size and the kappa value of the varices bleeding risk between endoscopists and endoscopic ruler
[Time Frame: 2020/11/13-2022/11/13]
- Secondary Outcome Measure:
- 2. The ICC value of the varix size and the kappa value of the varices bleeding risk among endoscopists
[Time Frame: 2020/11/13-2022/11/13]
 - 3. The bleeding rate of endoscopic ruler
[Time Frame: 2020/11/13-2022/11/13]
 - 4. The timing of endoscopic ruler
[Time Frame: 2020/11/13-2022/11/13]
 - 5. The correlation coefficient between varices size and hepatic venous pressure gradient
[Time Frame: 2020/11/13-2022/11/13]
 - 6. The correlation coefficient between varices size and decompensated events
[Time Frame: 2020/11/13-2022/11/13]

Eligibility

- Study Population: The investigators prospectively recruit well-defined participants with liver cirrhosis from university hospitals. Esophagogastroduodenoscopy is performed by a dedicated endoscopist at each center. Varices size is evaluated by the endoscopist and endoscopic ruler.
- Sampling Method: Probability Sample
- Minimum Age: 18 Years
- Maximum Age: 75 Years
- Sex: All
- Gender Based: No
- Accepts Healthy Volunteers: No
- Criteria: Inclusion Criteria:
- age between 18 and 75 years
 - clinically evident or biopsy-confirmed cirrhosis
 - Varices diagnosed by endoscopy
 - written informed consent
- Exclusion Criteria:
- red sign

Contacts/Locations

Central Contact Person: Xiaolong Qi, M.D.
Telephone:
Email:

Central Contact Backup: Yifei Huang, M.D.
Telephone:
Email:

- Study Officials: Xiaolong Qi, M.D.
Study Chair
LanZhou University
- Fengmei Wang, M.D.
Study Principal Investigator
Tianjin Second People's Hospital
- Guoxin Zhang, M.D.
Study Principal Investigator
The First Affiliated Hospital with Nanjing Medical University
- Shengjuan Hu, M.D.
Study Principal Investigator
People's Hospital of Ningxia Hui Autonomous Region
- Xianmei Meng, M.D.
Study Principal Investigator
The Second Affiliated Hospital of Baotou Medical College
- Xiaoyan Wang, M.D.
Study Principal Investigator
The Third Xiangya Hospital of Central South University
- Zhijie Feng, M.D.
Study Principal Investigator
The Second Hospital of Hebei Medical University
- Muhan Lv, M.D.
Study Principal Investigator
The Affiliated Hospital Of Southwest Medical University
- Yiling Li, M.D.
Study Principal Investigator
First Hospital of China Medical University

- Locations: **China**
- The first hospital of Lanzhou university
[Not yet recruiting]
Lanzhou, China
Contact: Xiaolong Qi, M.D.
- Tianjin Second People's Hospital
[Not yet recruiting]
Tianjin, China
Contact: Fengmei Wang, M.D.
- The First Affiliated Hospital with Nanjing Medical University

[Not yet recruiting]
Nanjing, China
Contact: Guoxin Zhang, M.D.

People's Hospital of Ningxia Hui Autonomous Region
[Recruiting]
Yinchuan, China
Contact: Shengjuan Hu, M.D.

The Second Affiliated Hospital of Baotou Medical College
[Not yet recruiting]
Baotou, China
Contact: Xianmei Meng, M.D.

The Third Xiangya Hospital of Central South University
[Not yet recruiting]
Changsha, China
Contact: Xiaoyan Wang, M.D.

The Second Hospital of Hebei Medical University
[Not yet recruiting]
Shijiazhuang, China
Contact: Zhijie Feng, M.D.

IPDSharing

Plan to Share IPD: Undecided

References

Citations: Qi X, Berzigotti A, Cardenas A, Sarin SK. Emerging non-invasive approaches for diagnosis and monitoring of portal hypertension. *Lancet Gastroenterol Hepatol.* 2018 Oct;3(10):708-719. doi: 10.1016/S2468-1253(18)30232-2. PubMed 30215362

Cremers I, Ribeiro S. Management of variceal and nonvariceal upper gastrointestinal bleeding in patients with cirrhosis. *Therap Adv Gastroenterol.* 2014 Sep;7(5):206-16. doi: 10.1177/1756283X14538688. PubMed 25177367

Bendtsen F, Skovgaard LT, Sorensen TI, Matzen P. Agreement among multiple observers on endoscopic diagnosis of esophageal varices before bleeding. *Hepatology.* 1990 Mar;11(3):341-7. doi: 10.1002/hep.1840110302. PubMed 2312048

Cales P, Pascal JP. Gastroesophageal endoscopic features in cirrhosis: comparison of intracenter and intercenter observer variability. *Gastroenterology.* 1990 Oct;99(4):1189. doi: 10.1016/0016-5085(90)90652-h. No abstract available. PubMed 2203663

Links:

Available IPD/Information: