



Clinical Trial Details (PDF Generation Date :- Sat, 21 Apr 2018 04:30:14 GMT)

CTRI Number	CTRI/2011/12/002253 [Registered on: 19/12/2011] - Trial Registered Retrospectively		
Last Modified On	13/11/2013		
Post Graduate Thesis	No		
Type of Trial	PMS		
Type of Study	Drug		
Study Design	Other		
Public Title of Study	Heptral Observational study in patient with Alcoholic Liver Disease		
Scientific Title of Study	A Prospective Multicenter Observational Study to Characterize the Patient Population with Cholestasis in Chronic Liver Disease due to Alcoholic liver disease receiving Heptral in India.		
Secondary IDs if Any	Secondary ID	Identifier	
	P13-162	Protocol Number	
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator		
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Abbott			
Primary Sponsor	Primary Sponsor Details			
Name	Abbott India Limited			
Address	Abbott India Limited - Clinical Operations Sion-Trombay Road, 3-4, Corporate Park,, Mumbai, Maharashtra 400 071 India			
Type of Sponsor	Pharmaceutical industry-Global			
Details of Secondary Sponsor	Name	Address		
	NIL	NIL		
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**Details of Ethics
Committee**

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Alert EC-IEC, Thane, India	Approved	07/09/2011	Yes
Institutional Ethics Committee, Global Hospitals & Health City, Chennai, Tamil Nadu, India	Approved	14/10/2011	No

**Regulatory Clearance
Status from DCGI**

Status	Date
Not Applicable	No Date Specified

**Health Condition /
Problems Studied**

Health Type	Condition
Patients	Alcoholic Liver Disease with Intra Hepatic Cholestasis

**Intervention /
Comparator Agent**

Type	Name	Details
Intervention	Heptral	Generic Name: Ademetionine or S-adenosyl-L-methionine Dose & Frequency: As per approved labeled recommendations Duration: Minimum of 6 weeks, can be extended if required based on the investigators discretion
Comparator Agent	NA	NA

Inclusion Criteria

Inclusion Criteria



Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1) Chronic liver disease due to alcoholic liver disease as diagnosed by the physician 2) Intrahepatic cholestasis as diagnosed by the physician 3) Age 18 to 65 years. 4) Patients being prescribed Heptral according to local label. 5) Patients written authorization to provide data for the study.

Exclusion Criteria

Exclusion Criteria	
Details	1) Contraindications to Heptral treatment including hypersensitivity according to the local label. 2) Pregnancy 1-2 trimester or lactation. 3) Hepatocellular or metastatic liver carcinoma. 4) Severe liver disease including but not limited to ascites, hepatic encephalopathy, hypoalbuminemia, coagulopathy. 5) Other conditions that make the patients participation impossible (by investigator judgment). 6) Patients receiving any hepatotoxic medications

Method of Generating Random Sequence

Not Applicable

Method of Concealment

Not Applicable

Blinding/Masking

Not Applicable

Primary Outcome

Outcome	Timepoints
1. Demographic data underlying liver disease, diagnostic criteria of intrahepatic cholestasis. 2. Burden of disease in terms of Healthcare utilization & Workload effect 3. Reason(s) for prescribing Heptral	After 6 weeks of therapy

Secondary Outcome

Outcome	Timepoints
To better understand the effectiveness and the tolerability of ademetonine therapy in the patient population with cholestasis in chronic liver disease due to alcoholic liver disease.	6 weeks treatment

Target Sample Size

Total Sample Size=250
Sample Size from India=250

Phase of Trial

Post Marketing Surveillance

Date of First Enrollment (India)

24/09/2011

Date of First Enrollment (Global)

No Date Specified

Estimated Duration of Trial

Years=0
Months=9
Days=0

Recruitment Status of Trial (Global)

Not Applicable

Recruitment Status of Trial (India)

Completed

Publication Details

To be published in Indian and International Journals

Brief Summary

In India, ademetonine (Heptral) is approved for the management of intrahepatic cholestasis and liver diseases. While ademetonine (Heptral) has been available since the past few months in the Indian market,



there is limited information on its effectiveness in Indian patients with ALD in terms of improvement in hepatic function profile as well as regarding its safety, tolerability and compliance amongst Indian patients. Also, no data currently exist that characterize patient population with chronic liver disease due to alcoholic liver disease to whom Heptral is prescribed in India and there is limited understanding of the physician's decision making process at the start the of Heptral treatment. Hence this observational study was planned to include Indian patients with ALD who had been prescribed Heptral by their physicians, in accordance with dosing recommendations mentioned in Heptral package insert, with the objective to gain insight into effectiveness, safety-tolerability and compliance of the drug.

This is a non-interventional, prospective observational study in which Heptral is prescribed in the usual manner in accordance with the terms of the local marketing authorization with regards to dose, population and indication.