



Clinical Trial Details (PDF Generation Date :- Wed, 20 Jun 2018 17:19:39 GMT)

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



<b>Age From</b>	18.00 Year(s)
<b>Age To</b>	65.00 Year(s)
<b>Gender</b>	Both
<b>Details</b>	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**

<b>Exclusion Criteria</b>	
<b>Details</b>	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**

<b>Outcome</b>	<b>Timepoints</b>
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**

<b>Outcome</b>	<b>Timepoints</b>
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.