Clinical Trial Details (PDF Generation Date :- Sun, 24 Sep 2017 09:14:04 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)

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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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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

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
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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 ademetionine 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, ademetionine (Heptral) is approved for the management of intrahepatic cholestasis and liver diseases. While ademetionine (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.