A study to evaluate the prevalence and distribution of steatotic and fibrotic liver disease across India

Submission date	Recruitment status No longer recruiting	Prospectively registered		
24/07/2024		Protocol		
Registration date	Overall study status	Statistical analysis plan		
06/08/2024	Completed	[X] Results		
Last Edited 19/05/2025	Condition category Digestive System	Individual participant data		

Plain English summary of protocol

Background and study aims

Non-alcoholic fatty liver disease (NAFLD) is a common liver condition where fat builds up in the liver. This can lead to more serious liver problems like non-alcoholic steatohepatitis (NASH), cirrhosis, and liver failure. In India, the rates of NAFLD are increasing due to rising obesity, type 2 diabetes, and metabolic syndrome. However, there's a lack of comprehensive data on how widespread NAFLD is across different regions of India. This study aims to fill that gap by using a non-invasive test called vibration-controlled transient elastography (VCTE) to measure liver fat and stiffness, helping us understand the prevalence and distribution of liver disease across the country.

Who can participate?

Adults over the age of 18 years who have consented to undergo the VCTE test for assessing liver health can participate in this study. Both men and women are eligible.

What does the study involve?

The study involves collecting data from patients who have already undergone the VCTE test between January 2023 and April 2024.

What are the possible benefits and risks of participating?

Participants will not experience direct benefits or risks from this study as it involves analyzing previously collected data. However, the findings could benefit the broader public by providing valuable insights into the prevalence of liver disease in India, potentially leading to better-targeted public health interventions and policies.

When is the study starting and how long is it expected to run for? May 2023 to April 2024

Who is funding the study? Zydus Healthcare Ltd (India)

Contact information

Type(s)

Principal investigator

Contact name

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Contact details

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Type(s)

Public, Scientific

Contact name

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Z2400301

Study information

Scientific Title

A retrospective cross-sectional observational multi-centric study to evaluate the prevalence and distribution of steatotic and fibrotic liver disease across India via vibration-controlled transient elastography parameters

Study objectives

There is a significant prevalence of steatotic and fibrotic liver disease across different regions of India, which can be accurately assessed using vibration-controlled transient elastography (VCTE) parameters controlled attenuation parameter (CAP) and liver stiffness measurement (LSM)

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 22/07/2024, Royal Pune Independent Ethics Committee (Office No. 13, Srv. No.81/A, Anupam Arcade, Opposite Snake Park, Katraj, Pune-Maharashtra, 411046, India; +91 (0) 72468233; royalpuneiec@gmail.com), ref: RPIEC410724

Study design

Retrospective cross-sectional observational multi-centric study

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Non-alcoholic fatty liver disease (NAFLD)

Interventions

The study involves collecting data from patients who have already undergone the VCTE test between January 2023 and April 2024.

Intervention Type

Other

Primary outcome(s)

Prevalence of steatotic and fibrotic liver disease measured using Vibration Controlled Transient Elastography (VCTE) parameters, including Controlled Attenuation Parameter (CAP) and Liver Stiffness Measurement (LSM). Data were collected retrospectively from patients who underwent VCTE between January 2023 and April 2024.

Key secondary outcome(s))

Analysis of age-wise and gender-wise distribution conducted using deidentified patient data. This data was retrospectively collected from January 2023 to April 2024.

Completion date

30/04/2024

Eligibility

Key inclusion criteria

- 1. Age > 18 years
- 2. Patients who have given consent for the FIBROSCAN™ (VCTE) test

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

90 years

Sex

All

Total final enrolment

13750

Key exclusion criteria

- 1. Pregnant or breastfeeding women
- 2. Individuals with alcohol consumption of more than 30 g and 20 g per day

Date of first enrolment

01/01/2023

Date of final enrolment

30/04/2024

Locations

Countries of recruitment

India

Study participating centre

Ananda Medicare

A Multi Speciality Medicare Hub

Gurudwara Sant Samagam, CSC-2, Adjoining DDA Market, Sector-9, Rohini, Delhi

New Delhi India 110085

Study participating centre Rudraksh Institute of Medical Science Rupala Complex, Nr Ghodasar BRTS, Ghodasar Ahmedabad India 380050

Study participating centre VIJAYRATNA TREATMENT CENTER

Sumeru Centre, Paldi Ahmedabad India 380007

Study participating centre Shivam Medi Care Clinic

Vrajbhumi Complex, Jodhpur Gam Rd, Satellite Ahmedabad India 380015

Study participating centre
Diabetes Care & Hormone Clinic
Gandhi Park, Nehru Nagar Cross Road
Ahmedabad
India
380015

Study participating centre APEX ENDOCRINE HOSPITAL

Pratik Complex Rajkot India 360002 Study participating centre Spandan Super Speciality Clinic India 431009

Study participating centre Sheetal Hospital India 425001

Study participating centre Manisha Universal Multispecialty Hospital India 400080

Study participating centre P. D. Hinduja Hospital India 400016

Study participating centre Kalpana lifeline hospital India 401201

Study participating centre Diabetes And Thyroid Care Centre India 400014

Study participating centre Diabetes Speciality Centre India 400057

P. D. Hinduja Hospital

Vashi India 402107

Study participating centre Jonota Doctors Clinic India

713101

Study participating centre Pratima Pharmacy India 731224

Study participating centre Monika Medical India 785001

Study participating centre Ananda Clinic India 700034

Study participating centre ADOPT CLINIC India 700089

Study participating centre Prathima Hospitals India 500027

RK HOSPITAL

India 506002

Study participating centre SSK HOSPITAL India 506167

Study participating centre Vijay Diabetes India 605005

Study participating centre K C MULTISPECIALITY HOSPITAL India 600071

Study participating centre Magna Centre India 600083

Study participating centre Narayanaa Hospital India 600084

Study participating centre Chennai Cardiac Care India 600050

Visakha Diabetes & Endocrine Centre India 530040

Study participating centre Advanced Centre for Endocrine & Diabetes India 530017

Study participating centre Lifecare Hospital and Research Centre India 560092

Study participating centre Spandana Clinic Multi Speciality & Diabetic Care Centre India 560097

Study participating centre Diacon Hospital India 560010

Study participating centre
Diascope Poly Clinics and Labs
India
560006

Study participating centre VISHWA HOSPITAL India 585401

K M C MANIPAL HOSPITAL

India 576104

Study participating centre Welmont Hospital

India 682017

Study participating centre Nidan Clinic

India 462024

Study participating centre Swasthya Hospital

India 474001

Study participating centre Blessing clinic

India 201009

Study participating centre Marya Clinic

India 110016

Study participating centre Stethohope Clinic

India 110092

saxena diabetic centre

India 305001

Study participating centre Sharma Hospital & Diagnostic Centre India 305002

Study participating centre Sashakt Thyroid Endocrinology & Diabetes Center India 302012

Study participating centre Dr Jay's Diabetes care India 313001

Study participating centre
Dr. Parminders Diabetes & Endocrine Centre
India
141001

Study participating centre Decent Hospital India 273001

Study participating centre Jai Clinic & Diabetes Care Center India 226003

SHUBHPRABHAT CLINIC

India 226010

Study participating centre Harsha Clinic and Diabetes Centre India 226005

Study participating centre Mayank medical centre India 226001

Study participating centre
Prarthana Clinic & Diabetes Care Centre
India
226007

Study participating centre Dr. Raj Memorial Clinic India 208001

Study participating centre Vinayak hospital India 284001

Study participating centre Max Super Speciality Hospital India 151001

Vimala Healthcare India 686631

Study participating centre Shreeyanta Diabetes & Metabolic Clinic India 380016

Study participating centre SHRI HASHU ADVANI MEDICAL CENTER India 400071

Study participating centre GOLAPBAG, BURDWAN India 713104

Study participating centre Dr Debraj Dey's Clinic India 784125

Study participating centre Life Care Diagnostics India 781325

Study participating centre K C MULTISPECIALITY HOSPITAL India 600071

S Kumaravel India

605001

Study participating centre Maruthi medical centre India 638112

Study participating centre Dr A Sahu India 221002

Study participating centre Dr Agarwal India 250002

Study participating centre Shekhar Hospital India 226016

Study participating centre Dr S K India 226016

Study participating centre Kanpur diabetes & medical centre India 208011

DM Endocrinology

India 462003

Study participating centre Dr A Sethia India 452001

Study participating centre Dr A K Panchola Clinic India 452002

Study participating centre Rajiv Ranjan (Chest Clinic) India 841301

Study participating centre C/O Diabetes Clinic India 800001

Study participating centre Positive Health Centre India 800001

Study participating centre
Dr. Santosh Kumar Singh's Clinic
India
800001

Dr. V K Jagnany India 834001

Study participating centre Dr Subhash Chandra Gupta India 282004

Study participating centre Bansal Nursing home India 282001

Study participating centre Ghaziabad India 201010

Study participating centre Nidaan Clinic India 201301

Study participating centre Internal Medicine Clinic India 110085

Study participating centre C/O, Bhatia Global Hospital India 110063

Dr V K Goel Clinic India 110018

Study participating centre Joy Nursing Home Pvt Limited India 110027

Study participating centre Dr Rohit kapoor India 143001

Study participating centre Dr T Aggarwal India 144001

Study participating centre DR GAURAV K SINGH CLINIC India 781301

Study participating centre Mahosadhi Medicine India 752002

Study participating centre New diabetes lifestyle disease clinic India 769042

MAHANANDA CLINIC

India 590017

Study participating centre Dr Pardiwalla's Clinic India 400036

Study participating centre Ananda Medicare India 110085

Study participating centre Life Line Sugar Clinic Kolkata India 700133

Study participating centre
AP Hospital - Diabetes Speciality Center
Coimbatore
India
641020

Study participating centre
Prabhu Diabetes & Multi-Specialty Center
Tiruchirappalli
India
620001

Study participating centre Care Hospital Agra

India 282002

Study participating centre Holy Help Hospital

Hisar India 125011

Study participating centre Central Railway Hospital

Jaipur India 302007

Study participating centre ESIC Model Hospital

Jaipur India 302006

Study participating centre Indra Hospital

Jagadhri, Haryana India 135003

Study participating centre Heart Line, Multi Speciality Hospital Panchkula India 134109

Study participating centre Kamboj Heart centre & Multi Speciality Hospital Jagadhri, Haryana

India 135003

Jammu Diabetes & Thyroid Care Center

Jammu India 180004

Study participating centre AMS NEOLIFE Superspeciality Clinic

Nagpada India 400008

Study participating centre Dr. Anand Kalaskar Clinic

Pune India 411044

Study participating centre Dr A R Kench

Pune India 411030

Study participating centre Dr. Dharmendra Panchal

Ahmedabad India 380013

Study participating centre Dr Ashutosh Jain

Meerut India 250110

Sponsor information

Organisation

Zydus Healthcare Ltd

Funder(s)

Funder type

Industry

Funder Name

Zydus Healthcare Ltd

Results and Publications

Individual participant data (IPD) sharing plan

The dataset generated during and/or analysed during the current study are not expected to be made available due to the retrospective nature of the study and deidentified data is being used solely for the purpose of understanding the prevalence and distribution of liver disease in India.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/05/2025	19/05/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes