

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

Submission date 24/07/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/08/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/05/2025	Condition category Digestive System	<input type="checkbox"/> 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)

Who is the main contact?

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Contact information

Type(s)

Principal investigator

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Public, Scientific

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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
Kalpna lifeline hospital
India
401201

Study participating centre
Diabetes And Thyroid Care Centre
India
400014

Study participating centre
Diabetes Speciality Centre
India
400057

Study participating centre

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

Study participating centre

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

Study participating centre

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

Study participating centre

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

Study participating centre

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

Study participating centre

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

Study participating centre

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

Study participating centre

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

Study participating centre

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

Study participating centre

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

Study participating centre

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

Study participating centre

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

Study participating centre

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