

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?

Dr Kunal Jhaveri, Kunal.Jhaveri@zyduslife.com

Contact information

Type(s)

Principal Investigator

Contact name

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Type(s)

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Cross sectional study

Study setting(s)

Care home, Hospital

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date

22/05/2023

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

90 Years

Sex

Both

Target number of participants

15520

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

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

Sponsor details

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Goregaon (East)

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India

400063

+91 (0)9601649741

Kunal.Jhaveri@zyduslife.com

Sponsor type

Industry

Funder(s)

Funder type

Industry

Funder Name

Zydus Healthcare Ltd

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/01/2025

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