

# Studying how safe and effective deriphyllin is for treating breathing problems in real-life settings across multiple hospitals

<b>Submission date</b> 14/05/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 26/05/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/09/2025	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study is looking at how safe and effective a medicine called Deriphyllin is for people with long-term breathing problems like asthma and chronic obstructive pulmonary disease (COPD). Deriphyllin is already used by many doctors because it helps open up the airways and reduce inflammation, but there isn't much information about how well it works in everyday medical settings. This study aims to fill that gap by collecting real-world data from patients across India.

### Who can participate?

Adults aged 18 years or older who have been newly prescribed deriphyllin by their doctor as an extra treatment for asthma or COPD can take part. People who have used deriphyllin before, or who have certain health conditions like serious heart problems, seizures, severe liver disease, or stomach ulcers, cannot join. Pregnant or breastfeeding women are also not eligible.

### What does the study involve?

Participants will continue their usual treatment as decided by their doctor - nothing will be changed or randomly assigned. Over a period of up to 3 months, they will have regular health checks. These include breathing tests, walking tests, blood tests, heart monitoring, and surveys about symptoms and satisfaction with treatment. Doctors will also keep track of any side effects.

### What are the possible benefits and risks of participating?

Participants may benefit from close monitoring of their health during the study. Their involvement could also help improve treatment for others with similar breathing problems. The risks are minimal and mostly relate to known side effects of Deriphyllin, such as nausea, trouble sleeping, or heart-related symptoms.

### Where is the study run from?

The study is being carried out at 200 clinics and hospitals across India. It is coordinated by a company called Tatvacare.

When is the study starting and how long is it expected to run for?

The study will last for 6 months in total. This includes 3 months to enroll participants and up to 3 months of follow-up for each person.

Who is funding the study?

The study is sponsored by Zydus Healthcare Limited, a pharmaceutical company based in Mumbai, India.

Who is the main contact?

The main contact for the study is Dr. Kunal Jhaveri from Zydus Healthcare Limited. He can be reached by email at [kunal.jhaveri@zyduslife.com](mailto:kunal.jhaveri@zyduslife.com)

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Kunal Jhaveri

### ORCID ID

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### Contact details

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India

400063

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[Kunal.Jhaveri@zyduslife.com](mailto:Kunal.Jhaveri@zyduslife.com)

### Type(s)

Public, Scientific

### Contact name

Dr Prachi Sharma

### Contact details

Digicare Healthcare Solutions Private Limited

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380058

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[patientsafety@tatvacare.in](mailto:patientsafety@tatvacare.in)

## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

PN/DERI0612/06

## Study information

### Scientific Title

Evaluating the safety and effectiveness of deriphyllin in respiratory disorders: a real-world multicentric study

### Acronym

DERI-RWE

### Study objectives

Deriphyllin, when used in routine clinical practice, is safe and effective in improving respiratory function and symptom control among patients with asthma, COPD, and other chronic respiratory conditions.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 22/04/2025, Central Independent Ethics Committee (Gini Aria, A 703, S No. 16/2/2A/1, Kondhwa Annex, Opposite Kjei Trinity College, Kondhwa Budruk, Pune, 411048, India; +91 9975167908; info@centraliec.com), ref: ECR/390/Indt/MH/2024

### Study design

Observational prospective multi-centre study

### Primary study design

Observational

### Study type(s)

Safety, Efficacy

### Health condition(s) or problem(s) studied

Chronic respiratory condition

### Interventions

- Tab. Deriphyllin 300 mg SR
- Tab. Deriphyllin 450 mg SR
- Tab. Deriphyllin Retard 150 mg
- Tab. Deriphyllin Retard 300 mg

Participants enrolled in this real-world observational study will be adult patients ( $\geq 18$  years) with chronic respiratory conditions such as asthma or COPD who are newly prescribed Deriphyllin by

their treating physician. After providing informed consent, participants will undergo baseline assessments, including vital signs, respiratory function tests (spirometry, 6-minute walk test), symptom questionnaires (mMRC, CAT, ACT), ECG, and laboratory tests (CBC, liver enzymes, serum bilirubin, and creatinine).

Participants will be followed up over a period of 12 weeks (3 months). During this follow-up period, one or two additional visits will be conducted (Visit 1 and Visit 2, if applicable) to repeat clinical assessments and monitor for adverse events. At each follow-up visit, respiratory parameters, symptom control, ECG, laboratory tests, physician assessments, and patient satisfaction will be evaluated.

No investigational intervention is assigned by the study team; deriphyllin is prescribed as part of routine clinical care. Data collection is purely observational and non-interventional.

Total duration of observation per participant: 12 weeks

Total duration of follow-up per participant: 12 weeks from enrolment

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Deriphyllin

### **Primary outcome(s)**

Adverse events/serious adverse events (SAEs): description, severity, seriousness, outcome and causality, measured using investigator assessment and spontaneous patient reporting, continuously monitored from baseline through all study visits

### **Key secondary outcome(s)**

1. Spirometry parameters: FEV1 (L), FEV1/FVC ratio (%), PEF (L/min) measured using a calibrated spirometer at baseline to follow-up visits within 3 months of baseline
2. Distance walked (meters) in a standard 6-Minute Walk Test (6MWT) conducted per ATS guidelines at baseline to follow-up visits within 3 months of baseline
3. Symptom severity for COPD measured using mMRC dyspnea score (0–4) at baseline to follow-up visits within 3 months of baseline
4. COPD Assessment Test (CAT) at baseline to follow-up visits within 3 months of baseline
5. Asthma Control Test (ACT) at baseline to follow-up visits within 3 months of baseline
6. Clinician-assessed disease status (e.g., improved/stable/worsened) measured using Global Physician Assessment, investigator's clinical judgment recorded in CRF at Visit 1 (within 3 months), visit 2 (within 3 months, if any)
7. Subject satisfaction score (e.g., on a 5-point Likert scale) at Visit 1 (within 3 months), Visit 2 (within 3 months, if any)
8. Vital signs: oxygen saturation (%), blood pressure (mmHg), pulse rate (bpm) measured using pulse oximeter and automated blood pressure monitor at baseline to follow-up visits within 3 months of baseline
9. Laboratory parameters: CBC (Hb, WBC, platelets, etc), liver enzymes: ALT, AST, GGT (U/L), serum bilirubin (mg/dL), serum creatinine (mg/dL) measured using standard automated laboratory assays from venous blood samples at baseline to follow-up visits within 3 months of baseline

10. 12-lead ECG tracing and interpretation measured using a standard ECG machine at baseline to follow-up visits within 3 months of baseline

**Completion date**

31/05/2026

## Eligibility

**Key inclusion criteria**

1. Patients aged >18 years of either gender
2. Patients with respiratory conditions such as asthma, COPD, and other conditions who are receiving deriphyllin treatment at the discretion of the treating physician
3. Patients for whom deriphyllin is being newly initiated as an add-on to ongoing therapy and who have not received deriphyllin treatment prior to study enrollment

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Patients under 18 years of age
2. Patients with known hypersensitivity to theophylline, etofylline, or any other components of deriphyllin, or those using other methylxanthines (e.g., aminophylline)
3. Patients with significant cardiovascular conditions like arrhythmia, LVH with EF < 30%, and severe heart failure
4. Patients diagnosed with active peptic ulcers due to the potential exacerbation of gastrointestinal symptoms
5. Patients having a history of epilepsy or other seizure disorders
6. Patients with severe liver dysfunction
7. Pregnant and lactating females
8. Any other conditions which are not suitable for Deriphyllin treatment at the discretion of the treating physician

**Date of first enrolment**

15/05/2025

**Date of final enrolment**

31/12/2025

# Locations

## Countries of recruitment

India

## Study participating centre

**Rehmania Nursing Home**

Bhiwandi

India

421202

## Study participating centre

**Dr Muddebihalkar Hospital**

Thane

India

400601

## Study participating centre

**G2 Clinics**

Mumbai

India

421003

## Study participating centre

**Bhanujyot Hospital**

Mumbai

India

421306

## Study participating centre

**Kapil Polyclinic**

Mumbai

India

400013

## Study participating centre

**Maniben Health Clinic**

Mumbai

India

400028

**Study participating centre**

**Bhavesb Ramesbcbandra Sbab**

Mumbai

India

400008

**Study participating centre**

**Shivanand Manjunab Nbak**

Mumbai

India

400004

**Study participating centre**

**Shivram Gopal Chitoor**

Mumbai

India

400084

**Study participating centre**

**Neelam Hospital**

Mumbai

India

400070

**Study participating centre**

**Dr. James General Clinic**

Mumbai

India

400078

**Study participating centre**

**Sagar J Raiya**

Mumbai

India

400080

**Study participating centre**

**Suma V Menon**

Sandor

India

401202

**Study participating centre**

**Abhinandan Clinic**

Mumbai

India

400067

**Study participating centre**

**DR. SAVLA DIABETIC & GENERAL CARE CLINIC**

Mumbai

India

400067

**Study participating centre**

**Kinjal Modi**

Mumbai

India

400092

**Study participating centre**

**Yashoda Clinic**

Mumbai

India

400060

**Study participating centre**



**Dr Subhash Bendres Clinic**  
Mumbai  
India  
400058

**Study participating centre**  
**Green Lung Clinic**  
Mumbai  
India  
400062

**Study participating centre**  
**Ulhas G Shirodkar**  
Mumbai  
India  
400058

**Study participating centre**  
**Sajwan Clinic**  
Rasayani  
India  
410207

**Study participating centre**  
**Mhatre Clinic**  
Alibag  
India  
402201

**Study participating centre**  
**Jaewale Hospital**  
Osmanabad  
India  
413501

**Study participating centre**

**Chavanda Hospital**

Latur  
India  
413512

**Study participating centre**

**Vivekananda Hospital**

Latur  
India  
413512

**Study participating centre**

**Vishal Ramesh More**

Pune  
India  
411015

**Study participating centre**

**Shree Laxmi Hospital**

Pune  
India  
411014

**Study participating centre**

**Dr. Pankaj Magar's Clinic**

Pune  
India  
411038

**Study participating centre**

**Shanarayan Clinic**

Pune  
India  
411035

**Study participating centre**

**Pawar Clinic**

Guhaghar

India

415703

**Study participating centre**

**Shree Healthcare**

Ratnagiri

India

415612

**Study participating centre**

**Cpr Hospital**

Kolhapur

India

416004

**Study participating centre**

**Spruha Chest Clinic**

Kolhapur

India

416004

**Study participating centre**

**Pankaj Multispeciality**

Sangli

India

416416

**Study participating centre**

**Satyajeet V Borade**

Sangli

India

416416

**Study participating centre**

**Rahul Rama Prabhudesai**  
Margao  
India  
403601

**Study participating centre**  
**Shwas Respiratory Clinic**  
Satara  
India  
415001

**Study participating centre**  
**Syed Tareque S Mhussain**  
Nagpur  
India  
440001

**Study participating centre**  
**Christanand Hospital**  
Brahmapuri  
India  
441206

**Study participating centre**  
**Dande Hospital**  
Nagpur  
India  
440010

**Study participating centre**  
**Saoji Hospital**  
Chikhali  
India  
443201

**Study participating centre**

**Gungewad Chest Clinic**

Aurangabad

India

431001

**Study participating centre**

**Niramaya Multispeciality Hospital**

Jalna

India

431203

**Study participating centre**

**Apeksha Hospital**

Nanded

India

431601

**Study participating centre**

**Gavasne Hospital**

Pune

India

413102

**Study participating centre**

**Urney Hospital**

Beed

India

431131

**Study participating centre**

**Kulkarni Hospital**

Sangamner

India

422605

**Study participating centre**

**Matoshri Hospital And Critical Care**  
Malegaon  
India  
423202

**Study participating centre**  
**Muktai Hospital**  
Nashik  
India  
422001

**Study participating centre**  
**Sapphire Hospital**  
Nashik  
India  
422001

**Study participating centre**  
**Lilawati Hospital**  
Nashik  
India  
422001

**Study participating centre**  
**Parsh Chest Clinic**  
Jalgaon  
India  
425001

**Study participating centre**  
**Hope Hospital**  
Akola  
India  
444001

**Study participating centre**

**Mohini Clinic & Day Care Centre**  
Murtizapur  
India  
444107

**Study participating centre**  
**Vittal Hospital**  
Washim  
India  
444505

**Study participating centre**  
**Gsl Medical College**  
Rajahmundry  
India  
533101

**Study participating centre**  
**Jabbilli Hospital**  
Rajahmundry  
India  
533102

**Study participating centre**  
**Delta Hospitals**  
Rajahmundry  
India  
533101

**Study participating centre**  
**Sri Chaitanya Clinic**  
Rajahmundry  
India  
533102

**Study participating centre**

**Vel Clinic**  
Madurai  
India  
625001

**Study participating centre**  
**Sri Ram Hospital**  
Rajapalyam  
India  
626117

**Study participating centre**  
**Maddur Medical Centre**  
Maddur  
India  
571428

**Study participating centre**  
**Ganesh Clinic**  
Gonikopa  
India  
571213

**Study participating centre**  
**Navdurga Daycare Center**  
Sardarsahar  
India  
331403

**Study participating centre**  
**Dr Sandeep Chest Clinic**  
Sardarsahar  
India  
331403

**Study participating centre**



**Dr Prabhat Clinic**

Jodhpur

India

342001

**Study participating centre**

**Bairwa Chest Clinic**

Barmer

India

344001

**Study participating centre**

**Tantia Hospital**

Sriganganagar

India

335001

**Study participating centre**

**Abdul Qayyum Ansary**

Jhalawar

India

326001

**Study participating centre**

**Goyal Chest & Tb Clinic**

Dholpur

India

328001

**Study participating centre**

**Nr Meena Clinic**

Gangapur City

India

322201

**Study participating centre**

**Saini Chest Clinic**

Hindaun City

India

322230

**Study participating centre**

**Navneet Clinic**

Udaipur

India

313001

**Study participating centre**

**Dr Bera Chest & Tb Clinic**

Pali

India

341001

**Study participating centre**

**Lalit Kumar Sharma**

Pali

India

306401

**Study participating centre**

**Anil Kumar Kumawat**

Pali

India

306401

**Study participating centre**

**Chawla Clinic**

Alwar

India

301001

**Study participating centre**

**Vijay Tb Clinic**

Tonk  
India  
304001

**Study participating centre**

**Chawda Clinic**

Indore  
India  
452001

**Study participating centre**

**CHL Hospital**

Indore  
India  
452001

**Study participating centre**

**Birla Hospital**

Indore  
India  
452001

**Study participating centre**

**Dr Ujjawal Sharma Clinic**

Owalior  
India  
474001

**Study participating centre**

**Dubey Nursing Home**

Chhindwara  
India  
480001

**Study participating centre**

**Dr Sunil Manohar Singh Prakash Medical**  
Rewa  
India  
486001

**Study participating centre**  
**Dr Pandey Clinic**  
Jabalpur  
India  
482001

**Study participating centre**  
**SMH Hospital**  
Bhopal  
India  
462025

**Study participating centre**  
**Sai Hospital**  
Bhopal  
India  
462025

**Study participating centre**  
**Rai Hospital**  
Sagar  
India  
470001

**Study participating centre**  
**Shree Clinic**  
Betul  
India  
460001

**Study participating centre**

**Saarathi Lung Clinic**

Vadodara

India

390007

**Study participating centre**

**Jagdish Clinic**

Vadodara

India

390007

**Study participating centre**

**Dr. Ankur Rawal Hospital**

Khambhat

India

388620

**Study participating centre**

**Nisarg Kishorkumar Oza**

Vadodara

India

390009

**Study participating centre**

**Iris Hospital**

Anand

India

388001

**Study participating centre**

**Madhuram Multispeciality Hospital**

Surat

India

395009

**Study participating centre**

**Sadhna Kutir Hospital**

Kim  
India  
394111

**Study participating centre**

**Haria L G Rotary Hospital**

Vapi  
India  
396195

**Study participating centre**

**Rangsai Clinic**

Vyara  
India  
394650

**Study participating centre**

**Bajrangdas Hospital**

Bhavnagar  
India  
364001

**Study participating centre**

**Jivandeep Hospital**

Mahuva  
India  
364290

**Study participating centre**

**Prajna Healthcare**

Ahmedabad  
India  
382424

**Study participating centre**

**Kishwa Hospital**

Modasa

India

383315

**Study participating centre**

**Shivam Hospital**

Palanpur

India

385001

**Study participating centre**

**Amrut Hospital**

Ahmedabad

India

380015

**Study participating centre**

**Shivkrupa Clinic**

Radhanpur

India

385340

**Study participating centre**

**Shaddha Clinic**

Radhanpur

India

385340

**Study participating centre**

**Viral Multispeciality Hospital**

Rajkot

India

360001

**Study participating centre**

**Mmpj Hospital**

Bhuj

India

370001

**Study participating centre**

**Divine Life Hospital**

Adipur

India

370205

**Study participating centre**

**H. J. Doshi Hospital**

Rajkot

India

370001

**Study participating centre**

**Prasad Health Care**

Bangalore

India

560028

**Study participating centre**

**Geetha Clinic**

Bangalore

India

560036

**Study participating centre**

**Sri Ganesh Clinic**

Bangalore

India

560078

**Study participating centre**



**Sumathi Clinic**

Bangalore

India

560062

**Study participating centre**

**United Medical Centre**

Bangalore

India

560102

**Study participating centre**

**Sri Sai Sanjeevini Clinic**

Bangalore

India

560102

**Study participating centre**

**Agara Chandrasekhar Raoshyam**

Bangalore

India

560040

**Study participating centre**

**Baby Memorial Hospital**

Kerala

India

670007

**Study participating centre**

**Wims Hospital**

Wayanad

India

673577

**Study participating centre**

**Thoovakunnu Clinic**

Kannur  
India  
670693

**Study participating centre**

**Mission Hospital**

Kannur  
India  
670105

**Study participating centre**

**St. Johns Hospital**

Kottayam  
India  
686014

**Study participating centre**

**Wellness Healthcare**

Ettumanoor  
India  
686631

**Study participating centre**

**Sree Aanjaneya Diabetic And Medical Center**

Kaviyoor  
India  
689582

**Study participating centre**

**Life Line Hospital**

Adoor  
India  
691554

**Study participating centre**

**Vimala Hospital**

Kanjoor  
India  
680575

**Study participating centre**

**M.a.j. Hospital**

Kochi  
India  
682024

**Study participating centre**

**St. Joseph's Hospital**

Kothamangalam  
India  
686691

**Study participating centre**

**Nirmala Medical Centre**

Muvattupuzha  
India  
686661

**Study participating centre**

**Mother Care Hospital**

Palakkad  
India  
678583

**Study participating centre**

**Karuna Medical College**

Palakkad  
India  
678103

**Study participating centre**

**St James Hospital**

Thrissur

India

680307

**Study participating centre**

**Neethi Clinic**

Thrissur

India

680732

**Study participating centre**

**Vani Clinic**

Coimbatore

641002

India

641002

**Study participating centre**

**Chest Hospital**

Kozhikode

India

673005

**Study participating centre**

**Alif Poly Clinic**

Malappuram

India

679357

**Study participating centre**

**Map Clinic**

Salem

India

636008

**Study participating centre**

**Ark Multispeciality Hospital**

Krishnagiri

India  
635001

**Study participating centre**  
**M Sankarganesh Masilamani**  
Shenbakkam  
India  
632004

**Study participating centre**  
**Jagannatham Clinic**  
Tirupati  
India  
517502

**Study participating centre**  
**P.b Clinic**  
Tirupati  
India  
517561

**Study participating centre**  
**Sri Venkataramana Cinic**  
Tirupati  
India  
517526

**Study participating centre**  
**Nataraj Clinic**  
Chittoor  
India  
517001

**Study participating centre**  
**Venkayya Clinic**  
Bangarupalem  
India  
517416

**Study participating centre**  
**Susheella Clinic**  
Palamaneru  
India  
517408

**Study participating centre**  
**Anandi Hospital**  
Madanapalle  
India  
517590

**Study participating centre**  
**Ramesh Babu Clinic**  
Tirupati  
India  
517502

**Study participating centre**  
**Sree Ras Clinic**  
Tirupati  
India  
517501

**Study participating centre**  
**Desu Clinic**  
Madanapalle  
India  
517325

**Study participating centre**  
**Rajiv Garg**  
Lucknow  
India  
226003

**Study participating centre**

**Kedar Nath Poddar**

Kolkata

India

700006

**Study participating centre**

**Apollo Multispeciality Hospitals**

Kolkata

India

700054

**Study participating centre**

**Civil Hospital Rd**

Sangli

India

416416

**Study participating centre**

**One Care Medical Center**

Coimbatore

India

641044

**Study participating centre**

**Sun Medical And Research Center**

Thrissur

India

680020

**Study participating centre**

**Parivar Hospital**

Gwalior

India

474009

**Study participating centre**

**Saluja Chest Care**

Meerut

India

250001

**Study participating centre**

**Navya Hospital**

Delhi

India

110043

**Study participating centre**

**Apollo Clinic**

Valasaravakkam

India

600087

**Study participating centre**

**P.sukumaran**

Kottayam

India

686001

**Study participating centre**

**Modi Clinic- Excellence In Chest & Ent**

Pune

India

411009

**Study participating centre**

**Health Harmony**

Mumbai

India

400064

**Study participating centre**



**Shilpa Medical Research Centre**  
Mumbai  
India  
400068

**Study participating centre**  
**Vora Clinic**  
Mumbai  
India  
400092

**Study participating centre**  
**Om Clinic**  
Mumbai  
India  
400062

## **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 data from this study is not expected to be made available. This decision is based on the proprietary nature of the research, as the study involves formulations and methods that are commercially sensitive and owned by the sponsor, Zydus Healthcare Limited.

### **IPD sharing plan summary**

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other files</a>	Full list of centres		08/09/2025	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>			20/05/2025	No	No