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

Submission date	Recruitment status Recruiting	Prospectively registered		
14/05/2025		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
26/05/2025 Last Edited	Ongoing Condition category	☐ Results		
		Individual participant data		
12/09/2025	Respiratory	[X] 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

Contact information

Type(s)

Principal investigator

Contact name

Dr Kunal Jhaveri

ORCID ID

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Contact details

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Type(s)

Public, Scientific

Contact name

Dr Prachi Sharma

Contact details

Digicare Healthcare Solutions Private Limited Ahmedabad India 380058 +91 (0)8290799906 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 (≥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 (%), PEFR (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

Maniben Health Clinic

Mumbai India 400028

Study participating centre Bhavesh Rameshchandra Shah

Mumbai India 400008

Study participating centre Shivanand Manjunath Nayak

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

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

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

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

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 Satyajieet V Borade

Sangli India 416416

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

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

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

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

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

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

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

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

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

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

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

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 Multispeaciality Hospital

Rajkot India 360001

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

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

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

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

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

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

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

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?
Other files	Full list of centres		08/09/2025	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			20/05/2025	No	No