

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

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

Contact information

Type(s)

Principal investigator

Contact name

Dr Kunal Jhaveri

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Type(s)

Public, Scientific

Contact name

Dr Prachi Sharma

Contact details

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India

380058

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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

Study participating centre

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

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
Guhagar
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

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?
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	