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

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|---|---|---|
| **Submission date**<br>14/05/2025 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol |
| **Registration date**<br>26/05/2025 | **Overall study status**<br>Ongoing | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>12/09/2025 | **Condition category**<br>Respiratory | [_] Individual participant data<br>[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

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### Type(s)
Public, Scientific

### Contact name
Dr Prachi Sharma

### Contact details
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# Additional identifiers

### Clinical Trials Information System (CTIS)

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**
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

**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 Multispeaciality 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 |
| Protocol file | | | 20/05/2025 | No | No |