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

Submission date
14/05/2025

Recruitment status
Recruiting

Registration date
26/05/2025

Overall study status
Ongoing

Last Edited
22/05/2025

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[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
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Type(s)
Public, Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Registry

Study setting(s)
Hospital

Study type(s)
Safety, Efficacy

Participant information sheet
No participant information sheet available

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

Pharmaceutical study type(s)
Pharmacodynamic

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Deriphyllin

Primary outcome measure
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

Secondary outcome measures
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

Overall study start date
22/04/2025

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
4000

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

Sponsor details
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Goregaon (East)
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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

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?
Protocol file			20/05/2025	No	No