Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 11:48:40 GMT)

CTRI Number	CTRI/2018/05/014065 [Registered on: 23/05/2018] - **Trial Registered Prospectively**
Last Modified On	26/10/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Biological
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	Efficacy and safety of R-TPR-024 / Lucentis® in patients with neovascular (wet) age-related macular degeneration
Scientific Title of Study	Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-024 / Lucentis® in patients with neovascular (wet) age-related macular degeneration

Secondary IDs if Any

Secondary ID	Identifier
RLS/OPT/2016/06 V 2, dated 23 Jan 17	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Reliance Life Sciences Pvt. Ltd.

Primary Sponsor

Primary Sponsor Details	
Name	Reliance Life Sciences Pvt Ltd
Address	Dhirubhai Ambani Life Sciences Centre Plot R-282, TTC Area of MIDC Thane Belapur Road Rabale, Navi Mumbai 400 701
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
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Dr Shachi Desai	Sanjivani Super Speciality Hospital Pvt. Ltd.	OPD No. 5, First floor, Uday Park Society, Near Sunrise Park, Vastrapur, Ahmedabad-380015 Ahmadabad GUJARAT	9978897564 drshachidesai@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee GSVM Medical College, Kanpur	Approved	22/06/2018	No
Ethics Committee of King George Medical University,Lucknow	Approved	12/06/2018	No
Ethics Committee, KLE University, Belgaum	Approved	20/04/2018	No
Institutional Ethics Committee KIMS	Approved	06/10/2018	No
Institutional Ethics Committee, , Dr. B R Ambedkar Medical College	Approved	25/08/2018	No
Institutional Ethics Committee, B J Medical College and Civil Hospital, Ahmedabad	Approved	17/12/2018	No
Institutional Ethics Committee, D Y Patil University School of Medicine	Approved	22/03/2019	No
Institutional Ethics Committee, Datta Meghe Institute of Medical Sciences	Approved	29/09/2018	No
Institutional Ethics Committee, JPM Rotary Club of Cuttack Eye Hospital and Research Institute, Cuttack	Approved	28/02/2019	No
Institutional Ethics	Approved	04/04/2019	No

Committee, King George Hospital			
Institutional Ethics Committee, Mysore Medical College and Research Institute and Associated Hospitals	Approved	10/09/2018	No
Institutional Ethics Committee, Regional Institute of Ophthalmology, Kolkata	Approved	05/06/2018	No
L V Prasad Eye Institute Ethics Committee	Approved	19/07/2018	No
Medilink Ethics Committee	Approved	17/12/2018	No
Narayana Nethralaya Ethics Committee	Approved	30/01/2019	No
Sanjivani Hospital Ethics Committee, Ahmedabad	Approved	27/02/2019	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	09/06/2017

Health Condition / Problems Studied

Health Type	Condition
Patients	neovascular (Wet) age related macular degeneration

Intervention / Comparator Agent

Type	Name	Details
Intervention	R-TPR-024	Ranibizumab 0.5 mg intravitreal injection every 4 weeks for 24 weeks
Comparator Agent	Lucentis®	Ranibizumab 0.5 mg intravitreal injection every 4 weeks for 24 weeks

Inclusion Criteria

Inclusion Criteria	
Age From	50.00 Year(s)
Age To	75.00 Year(s)
Gender	Both
Details	1. Male or female patients of age ? 50 years. 2. Active primary or recurrent subfoveal lesions with classic or occult choroidal neovascularization (CNV) secondary to age-related macular degeneration (AMD) in the study eye. 3. Best corrected visual acuity, using Early Treatment of Diabetic Retinopathy Study (ETDRS) charts, of 20/40 to 20/320 (Snellen equivalent) in the study eye.

Exclusion Criteria

Exclusion Criteria	
Details	1. Treatment with verteporfin photodynamic therapy in the study eye within 6 months or in the nonstudy eye within 1 week prior to randomization. 2. Previous external-beam radiation therapy, transpupillary thermotherapy or subfoveal focal laser photocoagulation in the study eye. 3. Laser photocoagulation (juxtafoveal or extrafoveal) in the study eye within 1 month prior to randomization. 4. CNV in either eye due to other causes, such as ocular

	histoplasmosis, trauma, or pathologic myopia. 5. Patients with controlled or uncontrolled diabetes mellitus.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Sequentially numbered, sealed, opaque envelopes
Blinding/Masking	Participant, Investigator, Outcome Assessor and Date-entry Operator Blinded

Primary Outcome

Outcome	Timepoints
proportion of patients who lost fewer than 15 letters in visual acuity	proportion of patients who lost fewer than 15 letters in visual acuity

Secondary Outcome

Outcome	Timepoints
immunogenicity, safety and tolerability of R-TPR-024 / Lucentis®	at week 24 from Baseline

Target Sample Size	**Total Sample Size=**159 **Sample Size from India=**159 **Final Enrollment numbers achieved (Total)=**159 **Final Enrollment numbers achieved (India)=**159
Phase of Trial	Phase 3
Date of First Enrollment (India)	12/07/2018
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	None Yet
Brief Summary	This prospective, multi-centre, double-blind, two-arm, parallel group, active control, randomized comparative clinical trial is being conducted to compare the efficacy and safety of R-TPR-024 vs. Lucentis® in patients with neovascular (wet) age-related macular degeneration (AMD).