Clinical Trial Details (PDF Generation Date :- Sun, 01 Oct 2023 04:22:08 GMT)

CTRI Number	CTRI/2018/02/011948 [Registered on: 19/02/2018] - **Trial Registered Prospectively**
Last Modified On	24/05/2022
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Diagnostic
Study Design	Single Arm Study
Public Title of Study	Study to assess safety, tolerability and effectiveness in patients with severe dementia exposed to exelon
Scientific Title of Study	A prospective, 16 week, phase IV study to evaluate safety, tolerability and effectiveness in patients with severe dementia of the Alzheimer's type exposed to rivastigmine (Exelon)15cm2 transdermal patch

Secondary IDs if Any

Secondary ID	Identifier
CENA713DIN01	Protocol Number

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

Details of Principal Investigator	
Name	
Designation	
Affiliation	
Address	
Phone	
Fax	
Email	

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Sneha Thakur
Designation	Lead Medical Advisor
Affiliation	Novartis India Limited
Address	The Inspire BKC Part of 601 & 701,G-Block, BKC Main Road, Bandra Kurla Complex, Bandra East, Mumbai The Inspire BKC Part of 601 & 701,G-Block, BKC Main Road, Bandra Kurla Complex, Bandra East, Mumbai - 400051 Mumbai MAHARASHTRA 400051 India
Phone	912250243632
Fax	912250243005
Email	sneha.thakur@novartis.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Sneha Thakur
Designation	Medical Advisor
Affiliation	Novartis India Limited
Address	The Inspire BKC Part of 601 & 701,G-Block, BKC Main Road, Bandra Kurla Complex, Bandra East, Mumbai The Inspire BKC Part of 601 & 701,G-Block, BKC Main Road, Bandra Kurla Complex, Bandra East, Mumbai - 400051 Mumbai MAHARASHTRA

	400051 India
Phone	912250243632
Fax	912250243005
Email	sneha.thakur@novartis.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Novartis India Limited, Medical Dept., Sandoz House, Shivsagar Estate, Dr. Annie Besant Road, Worli, Mumbai 400 018. INDIA.

Primary Sponsor

Primary Sponsor Details	
Name	Novartis India Limited
Address	The Inspire BKC Part of 601 & 701,G-Block, BKC Main Road, Bandra Kurla Complex, Bandra East, Mumbai
Type of Sponsor	Pharmaceutical industry-Global

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
Dr Kishalaya Karan	Apollo Multispecialty hospitals Ltd	58, Canal Circular road, Kolkata- 700054, West Bengal, India Kolkata WEST BENGAL	9231864907 drkishalaya@gmail.com
Dr Anil Ramakrishna	Bhagwan Mahaveer Jain Hospital	Room no.43, 1st floor, Old block,Neurology department, Millers road, Vasanth Nagar, Bangalore - 560 052 Bangalore KARNATAKA	9886256153 anilrb9@gmail.com
Dr Manoj Hunnur	BhaktiVedanta Hospital and Research Institute	Srishti Complex, BhaktiVedanta Swami Marg, Mira Road (East), Thane – 401107, Maharashtra, India Thane MAHARASHTRA	9867957022 02228459885 drhunnurmt@gmail.com
Dr Guruprasad Hosurkar	Columbia Asia Referral Hospital	Clinical research department, basement,26/4, Brigade gateway, Malleshwaram West, Beside Metro, Bangalore Bangalore KARNATAKA	09008933554 8030925688 guruhosurkar@gmail.com
Dr Debashis Chakraborty	Fortis Hospital	Room no. 106,Ground floor/Level 1, 730,Anandpur,Kolkata - 700107 Kolkata WEST BENGAL	9831172219 chakraborty_debashis@hotmail.com
Dr Hrishikesh Kumar	Institute of	Institute of	9874645445

	Neurosciences Kolkata	Neurosciences Kolkata, 185/1, Acharya Jagadish Chandra Bose Road, Park Street, Mullick Bazaar, Kolkata, West Bengal 700 017, India Kolkata WEST BENGAL	rishi_medicine@yahoo.com
Dr Annu Aggarwal	Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute	Medical Research department, 2nd floor,Rao Saheb Achutrao Patwardhan Marg, Four Bungalows, Andheri West, Mumbai - 400053 Mumbai (Suburban) MAHARASHTRA	9320192277 02230972030 annu.aggarwal@relianceada.com
Dr Sumitabh Gupta	M. V. Hospital and Research Centre	314/30, Mirza Mandi, Chowk, Lucknow – 226003, Uttar Pradesh, India Lucknow UTTAR PRADESH	7985349437 05224016051 drsumit.tmu@gmail.com
Dr Sushruth Vinaya Kumar	Santosh Hospital	6/1, Promenade Road, Near Coles Park, Bengaluru - 560005 Bangalore KARNATAKA	7760420485 08040848866 v.sushruth@gmail.com
Dr Anshu Rohatgi	Sir Ganga Ram Hospital	Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi – 110060, India North East DELHI	9810159406 01145041726 rohatgianshu@yahoo.com
Dr Rajesh Iyer	Vikram Hospital Private Limited	Neurology department,1st floor,#71/1,Millers Road, Opposite to St. Annes college, Bengaluru - 560052 Bangalore KARNATAKA	08071004500 rajeshbiyer@gmail.com
Dr Jaydip Ray Chaudhuri	Yashoda Hospital	Department of Neurology,1st floor,RajBhavan Road, Somajiguda, Hyderabad-500082,Telangana State, India Hyderabad ANDHRA PRADESH	09849007975 4023414613 jaydiprc@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Dr. Anil Ramakrishna - Bhagwan Mahaveer Jain Hospital, Human Ethics Committee	Approved	19/04/2018	No
Dr. Annu Aggarwal -	Approved	15/05/2018	No

Institutional Scientific & Ethics Board, Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute			
Dr. Anshu Rohatgi - Sir Ganga Ram Hospital Ethics Committee	Approved	31/03/2018	No
Dr. Debashish Chakraborty - Fortis Hospital Ethics Committeee	Approved	05/02/2018	No
Dr. Guruprasad Hosurkar - Institution Ethics Committee, Columbia Asia Referral Hospital	Approved	21/12/2017	No
Dr. Hrishikesh Kumar-Institute of Neurosciences Kolkatta-Institutional Ethics Commitee	Approved	24/07/2020	No
Dr. Jaydip Ray Chaudhuri - Institutional Ethics Committee, Yashoda Hospital	Approved	26/06/2018	No
Dr. Kishalaya Karan-Institutional Ethics committee, Apollo Multispecialty hospitals, Kolkata	Approved	22/01/2022	No
Dr. Malay Kant Singh - Institutional Ethics Committee for M.V. Hospital and Research Centre	Approved	25/02/2018	No
Dr. Manoj Hunnur - BhaktiVedanta Hospital Ethics Committee	Approved	09/04/2018	No
Dr. Rajesh Iyer - Vikram Hospital Pvt Ltd Bengaluru Ethics Committee	Approved	05/06/2018	No
Dr. Sushruth Vinaya Kumar - Institutional Ethics Committee of Santosh Hospital	Approved	21/09/2018	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	25/08/2017

Health Condition / Problems Studied

Health Type	Condition
Patients	Severe dementia of the Alzheimer’s type

Intervention / Comparator Agent

Type	Name	Details
Intervention	Rivastigmine 27 mg -15 cm2 transdermal patch	This is a multicenter, prospective, phase IV study evaluating safety, tolerability and effectiveness of

		rivastigmine 27 mg -15 cm2 transdermal patch prescribed in patients with severe dementia of the Alzheimer's type as per discretion of treating physician.
Comparator Agent	Not applicable	Not applicable

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	1)Patients willing to participate in the study by providing written informed consent. 2)Patients diagnosed with severe dementia secondary to Alzheimer's disease (AD) 3)Patient's prescribed with rivastigmine 27mg -15 cm2 transdermal patch as per discretion of treating physician

Exclusion Criteria

Exclusion Criteria	
Details	1)Contraindication as per PI 2)Patients simultaneously participating in other studies

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
To obtain safety data in patients with severe dementia of the Alzheimer's type treated with rivastigmine 27 mg -15 cm2 transdermal patch	Overall study period (from FPFV to LPLV)

Secondary Outcome

Outcome	Timepoints
1)To assess patients compliance to study medication 2)To assess the skin tolerability 3)To assess the proportion of patients with UTI 4)To evaluate treatment effect by rivastigmine 27 mg -15 cm2 transdermal patch by assessing the changes in MMSE 5)To evaluate treatment efficacy by rivastigmine 27 mg -15 cm2 transdermal patch by assessing the changes in ADCS-Activities of Daily Living Inventory – Severe Impairment Version (ADCS-ADL SIV) Score	During 16 weeks treatment period

Target Sample Size	**Total Sample Size=**102 **Sample Size from India=**102 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 4
Date of First Enrollment (India)	30/04/2018
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**2 **Months=**8 **Days=**0

Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	Publication will be done in November 2021
Brief Summary	The present phase IV study is mandated by Indian health authority (HA) as a part of conditional approval to market authorization of rivastigmine 27 mg -15 cm^2 transdermal patch for treatment of severe dementia secondary to Alzheimer's disease (AD). The HA mandated phase IV study in their approval letter. Due to non- availability of Indian data for rivastigmine 27 mg -15 cm^2 transdermal patch in severe dementia secondary to Alzheimer's disease (AD) patients, marketing authorization of the same has been granted condition to phase IV study. As per HA letter, interventional study is to be conducted. Thus the present 16 week study will be conducted to evaluate safety, tolerability and effectiveness in patients with severe dementia of the Alzheimer's type exposed to rivastigmine 27 mg -15 cm^2 transdermal patch as mandated by HA.