Clinical Trial Details (PDF Generation Date :- Mon, 07 Aug 2023 04:14:46 GMT)

CTRI Number	CTRI/2022/04/041667 [Registered on: 05/04/2022] - **Trial Registered Prospectively**
Last Modified On	21/02/2023
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	To see the effect and safety of Atropine sulfate 0.05% eye drops compared to Atropine sulfate 0.01% eye drops to decrease myopia progression in children
Scientific Title of Study	A Phase III, Multicentre, Randomized, Double-blinded, Parallel group, Comparative, Clinical Study to Evaluate the Efficacy and Safety of Atropine Sulfate 0.05% ophthalmic solution compared to Atropine Sulfate 0.01% ophthalmic solution for Controlling Progression of Myopia in Children

Secondary IDs if Any

Secondary ID	Identifier
BCR-EPL-002 Version 1.0 dated 07 Dec 2021	Protocol Number
CT/SND/007/2022	DCGI

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

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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
> Entod Pharmaceuticals Ltd. Ashirwad building, Opp. Badi Masjid, S V Road, Bandra (W) Mumbai 400050, Maharashtra, India

Primary Sponsor

Primary Sponsor Details	
Name	Entod Pharmaceuticals Ltd
Address	Ashirwad building, Opp. Badi Masjid, S V Road, Bandra (W) Mumbai 400050, Maharashtra, India
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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Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Dr.Shroff Charity Eye Hospital Ethics committe	Submittted/Under Review	No Date Specified	No
Ethics Committee, N.R.S. Medical College & Hospital Kolkata	Approved	19/12/2022	No
Ethics Committee, Tirupati Eye Centre & Research Institute	Approved	05/07/2022	No
Insitutional ethics Committee, Government Medical College, Jalgaon	Submittted/Under Review	No Date Specified	No
Institute Ethics Committee ,AIIMS, New Delhi	Approved	18/07/2022	No

Institute Ethics Committee AIIMS, Bhubaneshwar	Approved	21/09/2022	No
Institute Ethics Committee, Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh	Approved	22/10/2022	No
Institution Ethics Committee, B. J. Govt. Medical College and Sassoon General Hospitals	Submittted/Under Review	No Date Specified	No
Institutional Ethics committee GMC Srikakulam	Approved	12/12/2022	No
Institutional Ethics committee, Adichunchanagiri Hospital & Research Centre	Approved	17/05/2022	No
Institutional Ethics Committee, GSVM Medical College Kanpur	Approved	21/09/2022	No
Institutional Ethics Committee, Mysore Medical College & Research Institute and Associated Hospitals	Approved	23/04/2022	No
Mangala Institutional Ethics Committee	Approved	26/12/2022	Yes
Narayana Nethralaya Ethics Committee	Submittted/Under Review	No Date Specified	No
Niramaya Hospital Institute Ethics Committee	Approved	18/06/2022	No
V Care Independent Ethics Committee,	Approved	21/03/2022	Yes
Veracity Ethics Independent Ethics Committee	Approved	15/04/2022	Yes

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	28/02/2022

Health Condition / Problems Studied

Health Type	Condition
Patients	Myopia

Intervention / Comparator Agent

Type	Name	Details
Intervention	Atropine Sulfate 0.05% w/v ophthalmic solution	One drop to be instilled once a day preferably at night in each eye for 12 months
Comparator Agent	Atropine Sulfate 0.01% w/v ophthalmic solution	One drop to be instilled once a day preferably at night in each eye for 12 months

Inclusion Criteria

Inclusion Criteria

Age From	6.00 Year(s)
Age To	12.00 Year(s)
Gender	Both
Details	1. Male and female child subjects of age between 6 to 12 years (at the time of consenting). 2. Subjects with normal ocular health other than myopia. 3. Refractive error of spherical equivalent (SE) range of –0.50 D to ?6.00 D in both eyes. 4. Best-corrected distance visual acuity (BCDVA) 0.20 logMAR or better in both eyes. 5. The Investigator believes that the subject and subject's parent(s) or Legally Acceptable Representative(s) (LAR(s)) will comply with the requirements of the protocol. 6. Written informed consent /assent obtained from the subject and parent(s)/LAR(s) of the subject for participation in the study.

Exclusion Criteria

Exclusion Criteria	
Details	1.Current or previous myopia treatment with non-study atropine, pirenzepine or other topical anti-muscarinic agent. 2.Astigmatism of more than -1.5 D in either eye measured by cycloplegic autorefraction. 3.Allergy or hypersensitivity to atropine sulfate or excipients. 4.Abnormality of the cornea, lens, central retina, iris or ciliary body. 5.Current or prior history of ocular diseases (e.g., cataract, congenital retinal diseases, amblyopia, and strabismus. 6.Medical conditions predisposing patient to degenerative myopia, abnormal ocular refractive anatomy, and/or history of any other ocular diseases or ocular surgery. 7.History of any systemic diseases (e.g. cardiac, respiratory, endocrine, neurological, kidney or urinary disease or dysfunction). 8.Presence of a severe/serious ocular condition or any other unstable medical condition that in the investigators opinion may preclude study treatment or follow-up. 9.Participation in any study of an investigational, interventional product within 30 days prior to Screening Visit.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	An Open list of random numbers
Blinding/Masking	Participant, Investigator, Outcome Assessor and Date-entry Operator Blinded

Primary Outcome

Outcome	Timepoints
Mean change in spherical equivalent refractive error from baseline to 12 months, measured by cycloplegic autorefraction	12 Months

Secondary Outcome

Outcome	Timepoints
1.The proportion of subjects showing less than 0.50 D (spherical equivalent) myopia progression compared to baseline measured using cycloplegic autorefraction. 2.Mean change in ocular axial length from baseline to 12 months. 3.Mean change in pupil size from baseline to 12 months. 4.Mean change in accommodation amplitude (D) from baseline to 12 months 5.Mean change in visual acuity from baseline to 12 months.	12 months