Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 10:58:57 GMT)

CTRI Number	CTRI/2018/10/016053 [Registered on: 17/10/2018] - **Trial Registered Prospectively**
Last Modified On	22/04/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Efficacy and Safety of Enterogermina vs Placebo in Combination with ORT and Zinc for 5 Days Treatment in Children with Acute Diarrhea in India
Scientific Title of Study	A randomized, double blind, placebo controlled, parallel group, multicenter, comparative study to assess the efficacy and safety of spores of Enterogermina in combination with oral rehydration therapy (ORT) and Zinc versus placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute diarrhea in children

Secondary IDs if Any

Secondary ID	Identifier
LPS14914, version no 1, dated 19/06/2018	Protocol Number
U1111-1189-8467	Other

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

Details of Principal Investigator	
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Designation	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
> Sanofi Synthelabo India Private Limited Sanofi House, No 117 B, L and T Business Park, Saki Vihar Rd, Powai, Mumbai, Maharashtra 400072

Primary Sponsor

Primary Sponsor Details	
Name	Sanofi Aventis Groupe
Address	54 rue de la Boétie 75008 Paris- France
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 Amar Taksande	Acharya Vinoda Bhave Rural Hospital	Acharya Vinoda Bhave Rural Hospital, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Sawangi (M), Wardha-442004 Wardha MAHARASHTRA	9822369233 amar.taksande@gmail.com
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Dr Sharad Agarkhedkar	Padmashree Dr. D Y Patil HMedical College, Hospital and Research Centre- Pune	Research room, Ground floor, OPD number 16, OPD building Padmashree Dr. D Y Patil Medical College and Hospital, Pimpari, Sant Tukaram Nagar, Pune Maharashta - 411018 Pune MAHARASHTRA	9822030122 agarkhedkar@gmail.com
Dr Sushama Save	Topiwala National Medical College & B. Y. L. Nair Charitable Hospital	1st Floor, OPD Number 9, Room number 97, Pediatric Building, Topiwala National Medical College & B. Y. L. Nair Charitable Hospital,. Dr. A. L. Nair Road,. Mumbai - 400008 Mumbai MAHARASHTRA	9819096819 Sushmasave73@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee – Institute of Child health, Kolkata	Approved	09/12/2017	No
Ethics Committee, Padmashree Dr. D. Y. Patilmedical College,	Approved	15/03/2019	No

Hospital and Research Centre-Pune			
Ethics Committee-Mandya Institute of Medical Sciences, District Hospital Campus, Mandya	Approved	03/07/2019	No
Ethics Committee-M. S. Ramaiah Medical College and Hospitals, Bangalore	Approved	02/05/2019	No
Institutional Ethics Committee Topiwala National Medical College and B. Y. L. nair Charitable Hospital	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee- Era's Lucknow Medical College and Hospital, Lucknow	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee- Maulana Azad Medical College, New Delhi	Approved	03/12/2018	No
Institutional Ethics Committee-Padmashree Dr. D . Y Patilmedical College, Hospital and Research Centre-Mumbai	Approved	02/08/2018	No
Institutional Ethics Committee-Cloudnine Hospital, Bangalore	Approved	24/05/2019	No
Institutional Ethics Committee-Datta Meghe Institute of Medical Sciences	Approved	29/07/2019	No
Institutional Ethics Committee-Government Medical College, Nagpur	Approved	01/08/2019	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	01/10/2018

Health Condition / Problems Studied

Health Type	Condition
Patients	Irritable bowel syndrome with diarrhea
Patients	Irritable bowel syndrome with diarrhea

Intervention / Comparator Agent

Type	Name	Details
Intervention	Enterogermina®/Bacillus clausii /SSR29263	Enterogermina: 4 billion spores of Enterogermina per day (2 mini bottles per day, one in the morning and one in the evening) for a period of 5 days
Comparator Agent	aqueous suspension (each 5 mL mini bottle contains placebo)	Placebo: 2 mini bottles per day, one in the morning, one in the evening for a period of 5 days

Inclusion Criteria

Inclusion Criteria	
Age From	6.00 Month(s)
Age To	5.00 Year(s)
Gender	Both
Details	1 6 months less or equal to Age less than or equal to 5 years old 2 Suffering from acute diarrhea of less than 48 hours duration, Diarrhea is defined as unusual loose or watery stools at least 3 times in previous 24 hours period with no signs of dehydration or some dehydration WHO classification 3 Whose parent or legal guardian has given a written informed consent to participate for his or her child in the study at the time of enrollment

Exclusion Criteria

Exclusion Criteria	
Details	1 Known hypersensitivity to B clausii or any of the excipients or other probiotics 2 Children suffering from chronic GI disease as Crohn’s disease, hemorrhagic recto colitis, irritable bowel syndrome, short gut syndrome and inflammatory bowel disease 3 History of or current presence of blood hematochezia, pus, or mucus in stools within the previous 3 months 4 Persistent diarrhea a diarrhea episode which lasts more than 14 days

Method of Generating Random Sequence	Other
Method of Concealment	Centralized
Blinding/Masking	Participant and Investigator Blinded

Primary Outcome

Outcome	Timepoints
Duration of acute diarrhea (expressed in hours), as counted from the time of randomization up to recovery (the first normal stool as recorded according to Bristol score; a score 5 is described as normalization of stool)	Duration of acute diarrhea (expressed in hours), as counted from the time of randomization up to recovery (the first normal stool as recorded according to Bristol score; a score 5 is described as normalization of stool)

Secondary Outcome

Outcome	Timepoints
Safety: adverse event (AEs), including serious adverse event (SAE), adverse event of special interest (AESI) physical examination, and vital signs -Frequency of stool per day - Dehydration status evaluated per WHO classification	5 days

Target Sample Size	**Total Sample Size=**512 **Sample Size from India=**512 **Final Enrollment numbers achieved (Total)=**457 **Final Enrollment numbers achieved (India)=**457
Phase of Trial	Phase 3
Date of First Enrollment (India)	08/12/2018
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of	**Years=**2

Trial	**Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	None yet
Brief Summary	This randomized, double-blind, placebo-controlled, parallel group, multicenter, comparative study will assess the efficacy and safety of spores of Enterogermina in combination with oral rehydration therapy (ORT) and Zinc versus placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute diarrhea in children. The duration of diarrhea is the primary efficacy end-point.