bpni
putting child nutrition
at the forefront
of social change

Breastfeeding Promotion Network of India
(Registered Under Societies Registration Act XXI of 1860, Delhi R.No. S-23144)
BP-33, Pitampura, Delhi-110 034
Tel: (91) 011-27312705, 27312706, 42683059
Email: bpni@bpni.org
Website: www.bpni.org

BPNI/IMS Act/2019/002 **July 17, 2019**

To,
Dr. Harsh Vardhan
Hon'ble Minister
Ministry of Health and Family Welfare
Government of India
Delhi -110011

Sub: Violation of Section 9(2) "Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply & Distribution) Act 1992, and Amendment Act 2003" (IMS Act).

Dear Dr. Harsh Vardhan Ji,

India enacted the "Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply & Distribution) Act 1992, and Amendment Act 2003" (IMS Act) which came into force on August 1993. An offence committed under the law is cognizable.

The Government of India notified "Breastfeeding Promotion Network of India (BPNI)"wide No G.S.R. 540 (E), dated the 27th June 1994, to monitor the compliance with the above Act.

As per the section 9(2) of the IMS Act, "No producer, supplier or distributor referred to in sub-section (1), shall offer or give any contribution or pecuniary benefit to a health worker or any association of health workers, including funding of seminar, meeting, conference, educational course, contest, fellowship, research work or sponsorship".

Perusal of the clinical Trial Registry (Attached) maintained by the Indian Council of Medical Research (ICMR) has revealed **that Nestle India Limited, a producer of infant milk substitutes is sponsoring research titled "Multicentric Observational Study to Observe Growth in Preterm hospitalized infants" in following hospitals with their coordinators/principal investigators.**

Dr. Monjori Mitra of Medclin Research Pvt. Ltd, is the Trial Co-coordinator and Research Director Clinical Trial.

1. Cloudnine Hospital, Dr. R Kishore Kumar
2. Institute of Child Health, Kolkata, Dr. Apurba Ghosh.
3. Manipal Hospital, Bangalore, Dr. Ravi Shankar Swamy,
4. Sir Ganga Ram Hospital, New Delhi, Prof. Dr. Neelam Kler
5. The Calcutta Medical Research Institute, Kolkata, Dr. Saugata Acharyya

The study is not even approved by any independent. ethics committee.

Celebrating 25 Years bpni putting child nutrition at the forefront of social change 1991-2016

As a policy, BPNI does not accept funds of any kind from the companies manufacturing baby foods, feeding bottles etc. and from organization/industry having conflicts of interest.

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According to the legal opinion obtained by BPNI, Nestle India Limited and its concerned officials responsible for the conduct of its business, have infringed section 9(2) of the IMS Act. Participating hospitals in this research are also in violation of the IMS Act.

Therefore we request you to,

1. Initiate appropriate action against Nestle India Limited
2. Initiate action against the 5 hospitals
3. Stop the ongoing research immediately.
4. Direct DHR/ICMR to screen the trials for any infringement of national law.

We seek an appointment with you on any time convenient next week to personally brief you and seek your support for better enforcement of the IMS Act.

With regards,

Yours Sincerely,

Dr. Arun Gupta
Central Coordinator BPNI

Copy to: - Ms. Preeti Sudan, Secretary, Ministry of Health and Family Welfare,
Prof. Balram Bhargava,Secretary DHR & Director General, ICMR
Dr. Monjori Mitra, Research Director, Medclin Research Pvt. Ltd
Dr. R. Kishore Kumar, Cloudnine Hospital,
Dr. Apurba Ghosh, Institute of Child Health,
Dr. Ravi Shankar Swamy, Manipal Hospital,
Prof Dr. Neelam Kler,Sri Ganga Ram Hospital
Dr. Saugata Acharyya, the Calcutta Medical Research Institute

Encl Annex-1-copy clinical trial registry page CTR/2018/12/016715(Registered on: 18/12/018).

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Clinical Trial Details (PDF Generation Date :- Mon, 06 May 2019 07:14:01 GMT)

CTRI Number	CTRI/2018/12/016715 [Registered on: 18/12/2018] - **Trial Registered Prospectively**
Last Modified On	07/02/2019
Post Graduate Thesis	No
Type of Trial	Observational
Type of Study	Prospective observational
Study Design	Other
Public Title of Study	Multicentric, observational study to observe growth in Preterm hospitalized infants .
Scientific Title of Study	Growth and nutritional biomarkers in preterm infants in NICU – a Multicentric Study in India

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

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

Details of Principal Investigator	
Name	Dr Monjori Mitra
Designation	Research Director
Affiliation	Medclin Research Pvt. Ltd.
Address	Medclin Research Pvt. Ltd. Acropolis , Unit No. 10/5 , 10th floor 1858/1, Rajdanga main road Kolkata WEST BENGAL 700107 India
Phone	09831075734
Fax	
Email	monjorimr@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Monjori Mitra
Designation	Research Director
Affiliation	Medclin Research Pvt. Ltd.
Address	Medclin Research Pvt. Ltd. Acropolis , Unit No. 10/5 , 10th floor 1858/1, Rajdanga main road Kolkata WEST BENGAL 700107 India
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Phone	09831075734

Fax	
Email	monjorimr@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Nestle India Limited Nestlé House, Jacaranda Marg M Block DLF City Phase II, National Highway 8 Gurgaon 122 002, India

Primary Sponsor

Primary Sponsor Details	
Name	Nestle India Limited
Address	Nestlé House, Jacaranda Marg M Block DLF City Phase II, National Highway 8 Gurgaon 122 002, India
Type of Sponsor	Other [FMCG]

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 R Kishore Kumar	Cloudnine Hospital	Department of neonatalogy, 1533,9th Main,3rd Jayanagar, Bangalore- 560011, India Bangalore KARNATAKA	8066732259 drkishore@cloudninecare.com
Dr Apurba Ghosh	Institute of Child Health	Room No. 113, Project Room 11, Biresh Guha Street, Kolkata- 700017 Kolkata WEST BENGAL	9830052887 apurbaghosh@yahoo.com
Dr Ravi Shankar Swamy	Manipal Hospital	Department of neonatalogy, 98, HAL Airport Road, Bangalore -560017 Bangalore KARNATAKA	8025024632 raviswamy@manipalhospitals.com
Prof Dr Neelam Kler	Sir Ganga Ram Hospital	Department of Neonatology Institute of Child Health Sir Ganga Ram Hospital, New Delhi-110060 New Delhi DELHI	8447732229 drneelamkler@gmail.com
Dr Saugata Acharyya	The Calcutta Medical Research Institute	Department of Neonatalogy, 7/2, Diamond Harbour Road Kolkata- 700027 Kolkata WEST BENGAL	9830068567 saugata69@hotmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee of Manipal hospitals	Approved	04/02/2019	No
Ethics Department, Sir Ganga Ram Hospital	Approved	02/11/2018	No

Institutional Ethics Committee, The Calcutta Medical Research Institute	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee,Cloudnine Hospital, Bangalore	Approved	15/10/2018	No
Institutional Ethics Committee,Institute of Child Health	Approved	20/11/2018	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Disorders of newborn related to length of gestation and fetal growth

Intervention / Comparator Agent

Type	Name	Details

Inclusion Criteria

Inclusion Criteria	
Age From	0.00 Day(s)
Age To	1.00 Month(s)
Gender	Both
Details	Stable Preterm AGA infants born between 28 to 34 weeks of gestational age who are on enteral feeding. Singleton gestation

Exclusion Criteria

Exclusion Criteria	
Details	• On any other clinical study affecting nutritional management during the study period • Decision to not start minimum enteral feed within 48 hours of birth • Unable to obtain informed consent from parent (s) or legal guardian prior to the initiation of enteral feeding • Infants experiencing early onset sepsis (i.e. symptoms requiring antibiotic therapy and confirmed by a positive blood culture occurring before the 3rd day of life). • Presence of clinically significant congenital heart disease • Presence of any major congenital malformations, chromosomal abnormality or major gastro intestinal disease known to affect growth • Liver failure as detected by (if laboratory data is available) aspartate aminotransferase, alanine aminotransferase, gamma-glutamyl transferase, and direct bilirubin serum values 3-fold higher than reference range. • Peri-/intra-ventricular haemorrhage (grade 3-4 in Papille classification) determined using cranial ultrasonography, if it is performed. • Other serious disorders of cardiac/ respiratory/ endocrine/ hematological/ gastrointestinal/ other systems, or serious diseases requiring surgical intervention • Reasonable potential for early transfer to a non-study institution

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

Primary Outcome

Outcome	Timepoints

	Growth	Observation period for each infant will be the duration of hospital stay after the initiation of first enteral feed after enrollment in to the study.

Secondary Outcome

Outcome	Timepoints
Assessment of Feeding intolerance	Observation period for each infant will be the duration of hospital stay after the initiation of first enteral feed after enrollment in to the study.

Target Sample Size	**Total Sample Size=75** **Sample Size from India=75**
Phase of Trial	N/A
Date of First Enrollment (India)	01/01/2019
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=1** **Months=0** **Days=0**
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	The study result will be published in index journal post study completion
Brief Summary	This is an observational study to be conducted in preterm infants admitted in the NICU with the ..... age of 28 to 34 weeks. the primary objective of the study is to assess the growth outcomes and feeding intolerance observed in the Preterm infants. The study will be conducted in 5 tertiary care hospitals with NICU. The study period is 12 months approximately