Clinical Trial Details (PDF Generation Date :- Sat, 27 Nov 2021 21:41:29 GMT)

CTRI Number	CTRI/2017/01/007636 [Registered on: 06/01/2017] - **Trial Registered Prospectively**
Last Modified On	16/11/2019
Post Graduate Thesis	No
Type of Trial	Observational
Type of Study	Cross Sectional Study
Study Design	Single Arm Trial
Public Title of Study	Maternal Malnutrition and Lactation
Scientific Title of Study	Maternal Malnutrition and Lactation Performance 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 Sunita Taneja
Designation	Senior Scientist
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

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> National Institute of Health (NIH), BETHESDA MD 20817

Primary Sponsor

Primary Sponsor Details	
Name	Centre for Health Research and Development Society for Applied Studies
Address	45, Kalu Sarai, New Delhi – 110016, India
Type of Sponsor	Research institution

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 Sunita Taneja	Centre for Health Research and Development, Society for Applied Studies	Village Jatola, District Palwal, Tatarpur Faridabad HARYANA	011-46043751-55 011-46043756 sunita.taneja@sas.org.in

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics review committee Centre of Health Research and Development Society of Applied Studies	Approved	23/11/2015	No
Ethics review committee Centre of Health Research and Development Society of Applied Studies	Approved	04/01/2018	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Healthy mothers with breast feeding infants

Intervention / Comparator Agent

Type	Name	Details

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	45.00 Year(s)
Gender	Both
Details	- Married - Non-smoking -Women18-45 years of age with currently breastfeeding infants aged 2-4 months

Exclusion Criteria

Exclusion Criteria	
Details	- Participants not residing in study area for 2 weeks - Smoker - Non consent

Method of Generating Random Sequence

Not Applicable

Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
Lactation performance assessed by breastmilk volume body composition,Nutritional status of lactating mothers and infants,Breast milk macronutrient and micronutrient(percentage of fats, proteins, carbohydrates),Maternal micronutrient status. Immunological/inflammatory profiles of breast milk and its effect on infant, intestinal permeability.	At enrollment and on days 1,2,3,4,13 and 14

Secondary Outcome

Outcome	Timepoints
Examine raw food, urine, breastmilk samples for mycotoxin & pesticide. Interviews & FGD with community & FLW.	At enrollment and day 14

Target Sample Size	**Total Sample Size=**232 **Sample Size from India=**232 **Final Enrollment numbers achieved (Total)=**232 **Final Enrollment numbers achieved (India)=**232
Phase of Trial	N/A
Date of First Enrollment (India)	01/02/2017
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**2 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	-

Brief Summary

The study will be conducted in rural areas of Haryana. 232 lactating women, 18-45 years of age with breastfeeding infants aged 2 to 4 months will be enrolled over a period of a year. At enrollment information will be obtained on socio-demographic characteristics, breast feeding practices, maternal and infant morbidity. Mothers will be administered a single dose of deuterium oxide and the appearance and subsequent disappearance of deuterium in mothers and infants will be determined by serial salivary samples. Anthropometric measurements of infants and mothers will be taken at enrollment and 2 weeks later. Breast milk and blood samples will be taken at enrollment to ascertain the macro and micro nutrient status. Infant gut permeability will be assessed 2 weeks after enrollment.

Examine mycotoxin and pesticide exposure in the breast milk of mothers and mycotoxin exposure in infant urine in a sub sample. Also, estimate mycotoxin and pesticide exposure in food samples of rice, maize, groundnuts, chillies, sorgum/millet, seasonally available vegetables produce and milk samples (from retailer and wholesale vendors) commonly accessed by target communities.

In-depth interviews will be conducted (n=30) with already enrolled lactating women to comprehend characteristics of food systems, food safety and water, hygiene and sanitation access with respect to environmental exposures and dietary practices will be done. In-depth case studies (n = 15) and record GIS map for community and household food, wash access and practices will be done. Interviews with local shop owners (n =50) will be conducted for food safety practices, procurement, storage. Focus group discussions with community members (n = 10) to understand food systems affecting community members including potential routes of exposure to mycotoxins and pesticides, water, hygiene and sanitation access, use, practices and beliefs will be done.