Clinical Trial Details (PDF Generation Date :- Tue, 25 Feb 2020 07:41:07 GMT)

CTRI Number	CTRI/2016/11/007494 [Registered on: 25/11/2016] - **Trial Registered Prospectively**
Last Modified On	28/12/2019
Post Graduate Thesis	No
Type of Trial	Observational
Type of Study	Cross Sectional Study
Study Design	Other
Public Title of Study	The Effect of Vitamin B12 And/Or Folic Acid Supplementation in Early Childhood on Neurodevelopment; 6- 7 Years Later
Scientific Title of Study	The Effect of Vitamin B12 And/Or Folic Acid Supplementation in Early Childhood on Neurodevelopment; 6- 7 Years Later

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 and Deputy Director
Affiliation	Centre for Health Research and Development, Society for Applied Studies
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Details Contact Person (Scientific Query)

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Name	Dr Sunita Taneja
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Source of Monetary or Material Support

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> Thrasher Research Fund 15 W. South Temple Street, Suite 1650 Salt Lake City, UT 84101. The Research Council of Norway Drammensveien 288 P.O. Box 564 NO-1327 Lysaker, Norway.

Primary Sponsor

Primary Sponsor Details	
Name	Centre for Health Research and Development Society for Applied Studies
Address	45, Kalu Sarai South 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	661,Devli office, New Delhi 110080 South DELHI	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 for Health Research and Development, Society for Applied Studies	Approved	25/07/2016	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Children aged 5 to 8 years

Intervention / Comparator Agent

Type	Name	Details

Inclusion Criteria

Inclusion Criteria	
Age From	5.00 Year(s)
Age To	8.00 Year(s)
Gender	Both
Details	Children who participated in the trial in 2010-2011 and who consent to participate in the follow-up study

Exclusion Criteria

Exclusion Criteria	
Details	Non Consent

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

Primary Outcome

Outcome	Timepoints
-Weight height, skin fold thickness	-At enrolment (5 to 6 years after

Neurodevelopment and cognitive functioning through -Wechsler Intelligence Scale -Neuropsychological battery test -Behavior Rating Inventory of Executive Function -Strengths and Difficulties Questionnaire - Children's Sleep Habits Questionnaire - Micronutrient status:Hb, folate, cobalamin, holotranscobalamin, MMA, ferritin, vitD, transferrin receptor - Markers of metabolic diseases CRP, Leptin,adiponectin, HbA1c,VCAM-1,ICAM-1,Ghrelin	supplementation) -At enrolment (5 to 6 years after supplementation) -At enrolment (5 to 6 years after supplementation) -At enrolment (5 to 6 years after supplementation) -At enrolment (5 to 6 years after supplementation) -At enrolment (5 to 6 years after supplementation) -At enrolment (5 to 6 years after supplementation) -At enrolment (5 to 6 years after supplementation) -At enrolment (5 to 6 years after supplementation)

Secondary Outcome

Outcome	Timepoints
-	-

Target Sample Size	**Total Sample Size=**850 **Sample Size from India=**850 **Final Enrollment numbers achieved (Total)=**791 **Final Enrollment numbers achieved (India)=**791
Phase of Trial	N/A
Date of First Enrollment (India)	01/12/2016
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	Not Applicable
Brief Summary	This is an extension of the main study conducted in 2010 to 2011. Children enrolled in main study who were supplemented with folic acid and/or vitamin B12 for 6 months will be contacted. If consent is available assessment for cognitive functioning and neurodevelopment will be done. Anthropometric will be taken. Blood samples will be collected to assess the micronutrient status (Hemoglobin, folate, cobalamin, holotranscobalamin, methylmalonic acid, ferritin, vitamin D, transferrin receptor) and also markers of metabolic diseases will be analyzed [C-reactive protein, leptin, adiponectin, glycated hemooglobin (HbA1c), Vascular cell adhesion molecule-1 (VCAM-1), Intercellular adhesion molecule-1 (ICAM-1), Ghrelin]