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Improving the nutrition of pregnant women through a multiple micronutrient fortified salt

Submission date
14/02/2022

Recruitment status
No longer recruiting

Registration date
19/02/2022

Overall study status
Completed

Last Edited
22/11/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In a study in India, vitamin A deficiency was seen in over 50% of the children and this was reduced substantially and significantly by the use of a multiple micronutrient fortified salt. When an opportunity opened up to work towards the improvement of the nutrient status of pregnant women in the antenatal clinic serving the population from the same region, it was decided to improve the vitamin A status of these women too using the multiple micronutrient fortified salt. Since iodine fortification in salt is mandatory, it was decided to study urinary iodine too. The aim of this study is to improve serum retinol (vitamin A) and urinary iodine levels in pregnant women through the use of a multiple micronutrient fortified salt, enriched with iron, iodine, vitamin A, vitamin B1, B2, B6, B12, niacin and folic acid, in cooking meals.

Who can participate?
Pregnant women aged 19 to 29 years in the first trimester of pregnancy visiting the antenatal clinic of Kasturba Hospital, Gandhigram, Dindugal district in Tamilnadu, South India.

What does the study involve?
The women who visited the antenatal clinic will be recruited into the study and are allocated into the experimental or control group based on which week they will visit the antenatal clinic. The women will be enrolled into the experimental group in one week and the women will be enrolled into the control group in the next week. This process will continue until the required numbers of women are enrolled in the study. The women will be recruited into the study only if they are in the first trimester of their pregnancy based on the date of their last menstrual period. The women in the experimental group will receive a multiple micronutrient fortified salt enriched with vitamin A, iron, iodine, vitamin B1, B6, B12, niacin and folic acid. They will be given enough quantity of the fortified salt to last until their next visit to the clinic after 3 months. When they visit the hospital again after 3 months, they will be given enough quantity of fortified salt to last for another 3 months, until they deliver their babies. The women will be advised to use only the fortified salt in cooking all their meals. The women in the control group will not receive the fortified salt. One tablet of albendazole will be given to all the women in both groups in the 6th month of pregnancy. The women in both the experimental and control groups will be given iron and folic acid tablets which would last till their next hospital visit after 3 months. When they visit the hospital after 3 months, they will be given tablets to last for

another 3 months, until they deliver their babies. The researchers phone the women periodically to ascertain whether they are consuming only the tablets provided. This will be recorded in a separate notebook. The stability of the multiple micronutrient fortified salt will be tested in the laboratory in Chennai at 30C and 45% relative humidity. This has to be done to all the 12 batches of the fortified salt to be prepared for the study. The fortified salt has to be analysed for Vitamin A and iodine on the day it is manufactured and at 6 and 12 months later.
The women will be questioned on whether they experienced night blindness previously. They will be also questioned during their visit every trimester whether they are currently experiencing any episodes of night blindness. Details about the parity of the pregnancy of the women will be recorded during enrolment. Details of the age of the women, their occupation, and the occupation of their husbands will also be recorded. In the experimental group, when the women come to the clinic in their second and third trimester, they have to be questioned on the number of days the fortified salt was not used in the past 3 months. A dietary intake questionnaire will have to be completed once before the enrolment of the women into the study. Information is collected on the quantity of salt purchased per month by the woman, as well as the number of family members in her household. Blood samples will be collected from the women three times during the study in the first, second and third trimesters. Urine samples will be collected twice from the women when they are in the first trimester and third trimester. At the antenatal clinic of the hospital, after the registration process is completed, the phlebotomist will collect 5 ml of blood from the women (random sample). Urine specimens will also be collected from the women.

What are the possible benefits and risks of participating?
The experimental group will be given fortified salt to use in all the meals prepared. there are no risks involved in participating in this study.

Where is the study run from?
Kasturba Hospital (India)

When is the study starting and how long is it expected to run for?
May 2005 to June 2012

Who is funding the study?
Sight and Life (Switzerland)

Who is the main contact?
Dr Malavika Vinod Kumar
vinodkumar_m_k@hotmail.com

Contact information

Type(s)
Public

Contact name
Dr Malavika Vinod Kumar

ORCID ID
https://orcid.org/0000-0002-0427-512X

Contact details

6G Century Plaza
560/562 Anna Salai
Teynampet
Chennai
India
600018
+91 (0)9840323091
malavika@sundarserendipityfoundation.org

Type(s)
Scientific

Contact name
Dr Malavika Vinod Kumar

ORCID ID
https://orcid.org/0000-0002-0427-512X

Contact details
6G Century Plaza
560/562 Anna Salai
Teynampet
Chennai
India
600018
+91 (0)9840323091
malavika@sundarserendipityfoundation.org

Type(s)
Principal investigator

Contact name
Dr Malavika Vinod Kumar

ORCID ID
https://orcid.org/0000-0002-0427-512X

Contact details
6G Century Plaza
560/562 Anna Salai
Teynampet
Chennai
India
600018
+91 (0)9840323091
malavika@sundarserendipityfoundation.org

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2942008

Study information

Scientific Title
A study to improve the vitamin A and iodine status of pregnant women through a multiple micronutrient fortified salt

Study objectives
To improve serum retinol (vitamin A) and urinary iodine levels in pregnant women through the use of a multiple micronutrient fortified salt enriched with iron, iodine, vitamin A, vitamin B1, B2, B6, B12, niacin and folic acid, in cooking all meals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/06/2005, ethical committee of Sundar Serendipity Foundation (6G Century Plaza, 560/562 Anna Salai, Teynampet, Chennai 600018, India; +91 (0)9840323091; vinodkumar_m_k@hotmail.com), ref: 2942008

Study design
Single-center randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Vitamin A levels in the three trimesters and urinary iodine levels in the first and last trimester of pregnancy in pregnant women

Interventions
The women who visited the antenatal clinic were recruited into the study and would fall into the experimental or control group based on which week they visited the antenatal clinic. The women would be enrolled into the experimental group in one week and the women would be enrolled into the control group in the next week. This process continued until the required number of women were enrolled in the study. The women would be recruited into the study only if they were in the first trimester of their pregnancy based on the date of their last menstrual period.

The women in the experimental group received a multiple micronutrient fortified salt enriched with vitamin A, iron, iodine, vitamin B1, B6, B12, niacin and folic acid. They were given enough

quantity of the fortified salt to last till their next visit to the clinic after 3 months. The women were advised to use only the fortified salt in cooking all their meals. When the women in the experimental group visited the hospital again after 3 months, they were provided with the fortified salt again. The women in the experimental group were using the fortified salt in cooking all their meals, from their enrollment into the study in their first trimester, until they delivered their babies. The women in the control group did not receive the fortified salt.

One tablet of albendazole 400 mg in the 6th month of pregnancy was given to all the women in both groups. Deworming was carried out so that there were no worms competing for the micronutrients.

The women in both the experimental and control groups were given iron and folic acid tablets (each tablet containing 60 mg elemental iron and 400 micrograms of folic acid) which would last till their next hospital visit after 3 months. This was given to them again when they visited the hospital again after 3 months. All the women enrolled in this study were given iron and folic acid tablets from their enrollment in the first trimester, until they delivered their babies.

Intervention Type
Supplement

Primary outcome(s)
1. Serum vitamin A in the first, second and third trimester of pregnancy, measured by a rapid reverse-phase high-performance liquid chromatography (HPLC-Shimadzu, Japan) at baseline, midpoint after 3 months and endline after 6 months
2. Urinary iodine in the first trimester and third trimester of pregnancy, measured by spectrophotometry at baseline and endline after 6 months

Key secondary outcome(s))
1. The age and parity of the pregnant women collected using a questionnaire during enrollment into the study
2. Night blindness assessed using a questionnaire during enrollment into the study, and at the second- (midpoint after 3 months) and third-trimester visits (endline after 6 months) of the pregnant women to the hospital
3. The number of days the fortified salt was not used in the past 3 months in the experimental group, assessed by asking the women when they came to the clinic in their second (midpoint after 3 months) and third trimester (endline after 6 months)

Completion date
20/06/2012

Eligibility

Key inclusion criteria
1. Pregnant women
2. Aged 19 to 29 years
3. In the first trimester of pregnancy
4. Written informed consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
649

Key exclusion criteria
1. Pregnant women with hemoglobin less than 8 g/dl were excluded so that they could be treated immediately for anaemia
2. Women with current or previous gynecological problems

Date of first enrolment
12/05/2007

Date of final enrolment
18/07/2011

Locations

Countries of recruitment
India

Study participating centre
Kasturba Hospital
Gandhigram Trust
Gandhigram
Dindigul District
Tamilnadu
Chinnalapatti
India
624302

Sponsor information

Organisation
Sundar Serendipity Foundation

Funder(s)

Funder type
Research organisation

Funder Name
Sight and Life (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study are available upon request from Dr Malavika Vinod Kumar (email vinodkumar_m_k@hotmail.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/11/2022	22/11/2022	Yes	No