

Mumbai Maternal Nutrition Project

Submission date 11/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/03/2023	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

074048

Study information

Scientific Title

Mumbai Maternal Diet Study: randomised controlled trial of micronutrient-dense food before and during pregnancy to prevent low birthweight

Acronym

Project Saras

Study objectives

Supplementation of women with a food-based micronutrient-rich supplement for at least three months prior to conception, and throughout pregnancy, will reduce the incidence of low birthweight, reduce infant mortality, and improve functional outcomes in the children, including growth, neuro-cognitive function and cardiovascular disease risk factors.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. UK: Southampton and South West Hampshire Local Research Ethics Committee, 13/01/2003, ref: 377/02/t
2. Mumbai: BYL Nair and TN Medical College Ethics Committee, 17/09/2002

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Pregnancy outcome and infant mortality

Interventions

Women who are not pregnant, but are planning to have further children, will be recruited and randomised to one of four groups, to receive one of two interventions: a daily food-based supplement made from vegetables, fruit, and milk, of differing micronutrient content. Supplementation will be supervised. Field staff will record menstrual dates, in order to detect

pregnancy as early as possible. Women who become pregnant will have investigations during pregnancy, including blood samples and ultrasound scans.

Intervention Type

Supplement

Primary outcome measure

1. Birthweight
2. Infant mortality

Secondary outcome measures

1. Maternal micronutrient status
2. Maternal infection load and immune status
3. Foetal losses (miscarriages and stillbirths)
4. Newborn body composition
5. Newborn immune function

Overall study start date

09/01/2006

Completion date

31/03/2010

Eligibility**Key inclusion criteria**

1. Women living in slum communities in Bandra and Khar districts of Mumbai served by the Women of India Network (WIN) primary health care clinics
2. Women who wish to join
3. Married
4. Aged 15 to 35 years
5. Not pregnant at recruitment
6. Not using any PERMANENT form of contraception
7. Intending to have more children
8. Planning any future deliveries in Mumbai

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

4000

Total final enrolment

6513

Key exclusion criteria

1. Women living outside the study area
2. Non-married women
3. Women outside the age range specified
4. Women currently pregnant (these may become eligible after delivery)
5. Women who have undergone sterilisation surgery, or whose husbands have had a vasectomy
6. Women definitely not planning further pregnancies
7. Women definitely planning further deliveries outside Mumbai

Date of first enrolment

09/01/2006

Date of final enrolment

30/06/2009

Locations**Countries of recruitment**

England

India

United Kingdom

Study participating centre

Southampton General Hospital

Southampton

United Kingdom

SO16 6YD

Sponsor information**Organisation**

Centre for the Study of Social Change (India)

Sponsor details

MN Roy Human Development Campus

Plot 6, F Block

Opp Govt Colony 326

Bandra, Mumbai

India

400 051

+91 (0)22 30949666

rdpotdar@snehamrc.com

Sponsor type

Other

Funder(s)**Funder type**

Charity

Funder Name

Wellcome Trust

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

Funder Name

Parthenon Trust, ICICI Ltd (Mumbai)

Funder Name

The United States Agency for International Development (USAID)/The International Life Sciences Institute (ILSI) (USA)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan**

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2014		Yes	No
Results article	results	01/07/2016		Yes	No
Results article	results	01/07/2019	14/04/2020	Yes	No
Results article	Follow up results	07/01/2022	12/01/2022	Yes	No
Results article		18/02/2023	27/03/2023	Yes	No