

Effect of tempe and vitamin C rich fruit supplementation during pregnancy on iron status and pregnancy outcomes

Submission date 06/09/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 08/04/2008	Overall study status Completed	☐ Protocol
Last Edited 08/04/2008	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mrs Maria Wijaya-Erhardt

Contact details

Seameo-Tropmed RCCN-UI

Jl. Salemba Raya 6

Jakarta

Indonesia

10430

+62 21 3914017

mwijaya@seameo-rccn.org

Additional identifiers

Study information

Scientific Title

Study objectives

Does food-based intervention using tempe and vitamin C rich fruit during pregnancy improve the iron status?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Committee for Studies on Human Subjects, Faculty of Medicine, University of Indonesia.
Date of approval: 19/02/2007 (ref: 49/PTO2.FK/ETIK/2007)

Primary study design

Interventional

Study design

Randomised controlled single-centre trial (unit of randomisation: village).

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Anaemia during pregnancy

Interventions

The participating villages will be randomly allocated to the following two groups:

Supplementary group will receive supplementary food, 400 mg albendazole, and health and nutrition education. The average weekly supplementary food consist of: 600 g tempe (fermented soybean), 30 g red meat/dried anchovy/chicken liver, 45 g soy sauce, 350 g guava, 300 g papaya and 100 g orange. Supplementary food will be given daily at 12-20 week of gestation until delivery at home.

Control group will receive 400 mg albendazole only.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Tempe and albendazole

Primary outcome(s)

Maternal iron status at gestation 12-20 week:

1. Haemoglobin
2. Ferritin
3. Soluble transferrin receptors

Key secondary outcome(s)

1. Infectious status at gestation 12-20 weeks and 32-36 weeks:
 - 1.1. C-reactive protein
 - 1.2. A-1 acid glycoprotein
2. Helminth infestation (hookworms, A.lumbricoides, T.trichiura) measured quantitatively (eggs per gram) at gestation 12-20 weeks and 32-36 weeks
3. Gestational age calculated from date of last menstruation and palpation
4. Weight gain of pregnant women and birth weight of infant will be measured with electronic weighing scale
5. Length of infant will be measured with length board
6. Complication deliveries/fetal loss will be measured with verbal autopsy interviews, less than 3 days after delivery

Completion date

01/11/2008

Eligibility

Key inclusion criteria

1. Pregnant women, gestation 12-20 weeks
2. Age 15-49 years
3. No existing severe maternal illness

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Suffer from chronic disease
2. In medication/antibiotic treatment
3. Do not sign informed consent

Date of first enrolment

01/11/2007

Date of final enrolment

01/11/2008

Locations

Countries of recruitment

Indonesia

Study participating centre
Seameo-Tropmed RCCN-UI
Jakarta
Indonesia
10430

Sponsor information

Organisation
Nestle Foundation (Switzerland)

ROR
<https://ror.org/021k07d19>

Funder(s)

Funder type
Industry

Funder Name
Nestle Foundation (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration