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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

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)

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

Primary study design
Interventional

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 inform 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