

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

<b>Submission date</b> 06/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/04/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/04/2008	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Prevention

## Participant information sheet

## 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 measure**

Maternal iron status at gestation 12-20 week:

1. Haemoglobin
2. Ferritin
3. Soluble transferrin receptors

**Secondary outcome measures**

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

**Overall study start date**

01/11/2007

**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

**Age group**

Adult

**Sex**

Female

**Target number of participants**

250



**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)

**Sponsor details**

4, Place de la Gare

PO BOX 581

Lausanne

Switzerland

1001

+41 21 320 33 51

[nf@nestlefoundation.org](mailto:nf@nestlefoundation.org)

**Sponsor type**

Industry

**Website**

<http://www.nestlefoundation.org>

**ROR**

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



# **Funder(s)**

## **Funder type**

Industry

## **Funder Name**

Nestle Foundation (Switzerland)

# **Results and Publications**

## **Publication and dissemination plan**

Not provided at time of registration

## **Intention to publish date**

## **Individual participant data (IPD) sharing plan**

## **IPD sharing plan summary**

Not provided at time of registration