

The Four Pillars Approach in managing pregnant women with anaemia in Yogyakarta-Indonesia

Submission date 25/04/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 07/05/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/06/2014	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The Four Pillars Approach (FPA) is a new approach to anaemia in pregnancy combining four strategies to improve antenatal and delivery care. The main objective is to measure the effect of the FPA on pregnant women with anaemia.

Who can participate?

A total of 360 pregnant women with anaemia will participate.

What does the study involve?

The Four Pillars Approach was implemented in treatment groups and the usual care was implemented in control groups. The results of those interventions (Four Pillars Approach and usual care) were compared. The Four Pillars Approach is: healthy life style, social support, adequate skills and knowledge of nurse midwives of anaemia in pregnancy, and nurse midwives' caring behaviour. The participants in treatment groups were involved in parenting class and will receive a booklet of anaemia in pregnancy.

What are the possible benefits and risks of participating?

The participants received a regular haemoglobin (Hb) measurement and free consultation. There are no risks.

Where is the study run from?

The study ran from Yogyakarta, Indonesia.

When is the study starting and how long is it expected to run for?

The study started in mid 2012 and ran for a period of six months. The study can be extended if needed.

Who is funding the study?

Funded by Indonesian Government

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1083202989605930

Study information

Scientific Title

The Four Pillars Approach in managing pregnant women with anaemia in Yogyakarta-Indonesia

Acronym

FPA

Study objectives

It is hypothesised that the Four Pillars Approach will be effective in improving the outcomes for pregnant women with anaemia vs. usual care.

The null hypothesis is that there will be no difference in outcomes between treatment and control groups, this may arise participant's compliance on the treatment is not monitored by the trained nurse-midwives.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Medical and Health Research Ethics Committee (MHREC), Ministry of National Education
Faculty of Medicine Gadjah Mada University, December 15, 2011, ref: KE/FK/730/EC

Study design

Interventional case control study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

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

Anaemia in pregnancy

Interventions

In an intervention study, the effectiveness of the Four Pillars Approach will be compared to
usual care.

Training of the Four Pillars Approach to nurse midwives in treatment groups in Yogyakarta. The
trained nurse midwives will implement the Four Pillars Approach to eligible participants during
the period of six months. Participants will receive the booklet of anaemia in pregnancy and with
their husbands or other family members will involve in parenting classes.

In this study, we use different location for treatment and control groups, but they have the
similar characteristics of demography and population. We use 24 Public Health Center in each
groups. Based on the sample size calculation, we need 360 participants totally. The participants
enrollment will be done until the target number of participant in each Public Health Center is
achieved. We use cluster for the target number of participants in each Public Health center in
both groups, and we randomize the recruited participants.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. The difference of haemoglobin level
2. The number of antenatal care attendances
3. Skilled birth attendance at delivery

Haemoglobin level, the frequency of antenatal care will be measured at baseline (in first trimester of pregnancy) and after six months of intervention (in the third trimester of pregnancy); and the presence of skilled birth attendance during labour will be monitored in delivery process.

Secondary outcome measures

1. The barriers and facilitating factors of the implementation of the Four Pillars Approach
2. Patient's and nurse-midwives' satisfaction with the approach.

Evaluated after six months of intervention

Overall study start date

01/05/2012

Completion date

31/12/2012

Eligibility

Key inclusion criteria

1. Pregnant women with a haemoglobin (Hb) of less than 11 g/dl in the first trimester of pregnancy
2. Living with a husband or other family members

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

360

Key exclusion criteria

Pregnant women over twelve weeks of gestation will be excluded

Date of first enrolment

01/05/2012

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

Indonesia

Study participating centre

PSIK FK UGM

Yogyakarta

Indonesia

55281

Sponsor information**Organisation**

Radboud University Medical Centre Nijmegen (Netherlands)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.vrouwenstudiesgeneeskunde.nl/>

ROR

<https://ror.org/05wg1m734>

Funder(s)**Funder type**

Government

Funder Name

Directorate General of Higher Education Ministry of National Education of Republic of Indonesia (Indonesia) ref.: 369/E4.4/K/2011

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/05/2014		Yes	No