

# Iron supplementation in patients with anemia

<b>Submission date</b> 20/06/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/10/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/04/2023	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Anemia is a condition in which there are not enough healthy red blood cells to carry adequate oxygen to the body's tissues. It is treated with iron supplementation. Up to now, the blanket distribution of iron supplementation in Indonesia to reproductive-age women has continued with unsatisfactory results. The aim of the study is to evaluate the effectiveness of iron supplementation to increase hemoglobin levels.

### Who can participate?

Patients aged between 15–49 years with moderate or severe anemia

### What does the study involve?

Participants are randomly allocated to take iron tablets with folic acid or iron tablets with multivitamins for 30 days. Hemoglobin levels are measured at the start of the study and after 30 days

### What are the possible benefits and risks of participating?

Participants may benefit from a free medical check related to their anemia and treatment with iron supplementation. There is a risk of side effects from iron supplementation such as a gastrointestinal ulcer with different symptoms (nausea, vomiting)

### Where is the study run from?

1. Universitas Padjadjaran (Indonesia)
2. Ministry of Health in Teluk Bintuni, West Papua Province (Indonesia)

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

September 2018 to November 2019

### Who is funding the study?

1. Universitas Padjadjaran (Indonesia)
2. Teluk Bintuni Hospital (Indonesia)
3. Ministry for Research, Technology, and Higher Education (Indonesia)

### Who is the main contact?

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# Contact information

## Type(s)

Scientific

## Contact name

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## Protocol serial number

0719010092

# Study information

## Scientific Title

Adherence to iron supplementation in reproductive-age women with anemia in West Papua, Province, Indonesia

## Study objectives

Sociodemographic, adherence to iron supplementation, knowledge of anemia affected to anemia recovery level.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 15/02/2019, Padjadjaran University Research Ethics Committee (Jl. Prof. Eyckman Number 38, Bandung, 40161, Indonesia; +62 (0)22 2038697, kepk.fk.unpad@gmail.com), ref: 172/UN6.KEP/EC/2019

## Study design

Quasi-experimental study

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Moderate and severe anemia

## Interventions

Participants are randomised to take one of two oral supplements daily for 30 days. The iron fumarate-folic acid (IF-FA) supplement contains the elemental iron equivalent of 30 mg and 400 µg of folic acid. The iron gluconate-multivitamins (IG-MV) supplement contains the elemental iron equivalent of 0.9 mg, 500 µg of folic acid, and multivitamins, such as 15 mg vitamin B1 HCl, 0.25 mg vitamin B2, 0.25 mg vitamin B6 HCl, 12.5 mg vitamin C, 1.5 mg calcium pantothenate, 10 mg nicotinamide, 0.5 mg folic acid, 0.65 mg cupric sulfate, and 100 mg dried beef liver. Data is collected on the factors that influence medication adherence is obtained from the calculation of the remaining tablets given for 30 days; the Medication Adherence Rating Score (MARS) tool; and the participants' perspective on adherence. For biomarker observations, hemoglobin levels are measured pre and post intervention.

## Intervention Type

Supplement

## Primary outcome(s)

Hemoglobin level measured using the portable analyzer HemoCue 201 at baseline and 30 days

## Key secondary outcome(s)

Correlation factors to the success of anemia therapy such as ethnicity, adherence to MARS and pill counting methods, and the type of supplementation, measured at baseline and 30 days

## Completion date

29/11/2019

## Eligibility

### Key inclusion criteria

1. Moderate and severe anemia
2. Aged between 15–49 years
3. Consented to take part in the study

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Mixed

**Sex**

Female

**Total final enrolment**

110

**Key exclusion criteria**

1. Did not complete the informed consent
2. Incomplete data collected pre and post session
3. Unable to communicate

**Date of first enrolment**

01/10/2019

**Date of final enrolment**

30/10/2019

**Locations****Countries of recruitment**

Indonesia

**Study participating centre**

**Pusat Studi Genetik Medis, Fakultas Kedokteran Universitas Padjadjaran**

Jl. Prof. Eyckman N0. 38

Bandung

Indonesia

40161

**Sponsor information****Organisation**

Padjajaran University

**ROR**

<https://ror.org/00xqf8t64>

**Organisation**

Teluk Bintuni General Hospital

**Organisation**

## **Funder(s)**

### **Funder type**

University/education

### **Funder Name**

Universitas Padjadjaran

### **Alternative Name(s)**

Padjadjaran University, UNPAD

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

Universities (academic only)

### **Location**

Indonesia

### **Funder Name**

Teluk Bintuni Hospital

### **Funder Name**

Kementerian Riset Teknologi Dan Pendidikan Tinggi Republik Indonesia

### **Alternative Name(s)**

Ministry of Research, Technology and Higher Education, Kementerian Ristek Dikti, Kementerian Riset dan Teknologi

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

National government

### **Location**

Indonesia

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository <https://repository.unpad.ac.id/> (still in maintenance).

## IPD sharing plan summary

Stored in non-publicly available repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/01/2023	20/04/2023	Yes	No