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Iron supplementation in patients with anemia

Submission date
20/06/2022

Recruitment status
No longer recruiting

Registration date
25/10/2022

Overall study status
Completed

Last Edited
20/04/2023

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/09/2018

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

Age group
Mixed

Sex
Female

Target number of participants
222

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
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Sponsor information

Organisation
Padjadjaran University

Sponsor details
Department of Pharmacology and Clinical Pharmacy
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Sponsor type
University/education

Website
https://www.unpad.ac.id

ROR
https://ror.org/00xqf8t64

Organisation
Teluk Bintuni General Hospital

Sponsor details
Jl. Raya Sibena KM 7, Teluk Bintuni
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+62 (0)21 294 50 999
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Sponsor type
Hospital/treatment centre

Organisation
Indonesian Ministry for Research, Technology, and Higher Education

Sponsor details

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Sponsor type
Government

Website
https://kemendikbud.go.id

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

Publication and dissemination plan
Publication in the International Journal of Women's Health and Reproduction Sciences

Intention to publish date
17/08/2022

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?
Results article		01/01/2023	20/04/2023	Yes	No