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A multi-faceted intervention to improve syphilis screening and management in pregnant women in Indonesia: the DUALIS (Dual) study

Submission date
27/05/2025

Recruitment status
Not yet recruiting

Registration date
30/06/2025

Overall study status
Ongoing

Last Edited
15/09/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Mother-to-child transmission (MTCT) of syphilis, also called syphilis is the second leading cause of preventable stillbirths, second only to malaria. In pregnancy, syphilis increases the risk of problems like premature birth, brain damage, nerve damage and bone deformities in the baby. Mother-to-child transmission of syphilis (congenital syphilis) can be prevented by testing pregnant women early in pregnancy and giving treatment promptly if they test positive. Indonesia is reported to have the highest rate of syphilis among pregnant women. Between 2013 and 2023, the level of testing for syphilis among pregnant women rose from <1% to 37% with a positivity rate of 0.48%. Unfortunately, cases of congenital syphilis are on the rise because only 44% of women who currently test positive for syphilis receive treatment due to several challenges related to the health system. Our team will work with the Indonesian government and a leading implementing partner to adapt and evaluate a multifaceted intervention that will focus on improving how syphilis testing and treatment are offered during pregnancy in two provinces of Indonesia.

Who can participate?
Government primary health centres (Puskesmas) and their network of community and private midwives in Central Java and East Nusa Tenggara provinces in Indonesia will participate in the study.

What does the study involve?
We will design a multifaceted intervention to address barriers to screening and treatment for syphilis in pregnancy, evaluate the effectiveness of the intervention compared to current practice, evaluate the uptake and implementation of the intervention, and determine its cost-effectiveness.

What are the possible benefits and risks of participating?
Participating healthcare facility staff will receive training in effectively managing syphilis in pregnant women.
Pregnant women who are positive for syphilis who receive inadequate treatment and their

unborn babies, may benefit by receiving appropriate care when the research team notifies the healthcare staff through monthly reports.
Further, we hope that if our intervention is successful, more pregnant women will be screened, and if testing positive, then receive appropriate treatment, which will lead to improved health outcomes for women and newborns.

We do not expect any additional risks to study participants outside those associated with usual clinical care for patients, or with the usual work routine for health care staff. However, for the study evaluation interviews, discomfort, embarrassment or distress related to discussions about sexually transmitted infections could potentially occur.

Pregnant women may experience decreased mental health if their syphilis status is inadvertently disclosed because of the stigma associated with syphilis.

Where is the study run from?
This is a collaboration between Universitas Gadjah Mada, the London School of Hygiene and Tropical Medicine, United Kingdom (UK), and the Kirby Institute University of New South Wales, Australia.

When is the study starting and how long is it expected to run for?
August 2024 to September 2027

Who is funding the study?
Medical Research Council, UK.

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A multi-faceted intervention to improve syphilis screening and management in pregnant women in Indonesia: the DUALIS (Dual) study

Study objectives
A multi-faceted intervention to address operational and capacity barriers will accelerate scale-up of antenatal testing and treatment for syphilis in two provinces of Indonesia.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 27/08/2025, LSHTM Research Ethics Committee (Keppel Street, London, WC1E 7HT, United Kingdom; +44 20 7927 2221; ethics@lshtm.ac.uk), ref: 32017

2. approved 24/07/2025, Medical and Health Research Ethics Committee (MHREC) (Bulaksumur, Depok, Sleman Regency, Special Region of Yogyakarta, 55281, Indonesia; +62 8112666869; mhrec_fmugm@ugm.ac.id), ref: KE/FK/1217/EC/2025

3. submitted 15/09/2025, UNSW Human Research Ethics Committee (UNSW Sydney, Sydney, NSW 2052, Australia; +61 2 93851000; humanethics@unsw.edu.au), ref: iRECS10032

4. approved 08/07/2025, Komisi etik bidang kesehatan BRIN (Ethical Committee of Health of BRIN) (Jl. MH. Thamrin No. 8 Gd. BJ Habibie Lt. 8,, Jakarta Pusat, 10340, Indonesia; +62 811-1933-3639; klirensetik@brin.go.id), ref: 166/KE.03/SK/07/2025

Study design
Facility-based multi-centre two-arm parallel cluster randomized implementation trial

Primary study design
Interventional

Study type(s)
Prevention, Screening, Treatment

Health condition(s) or problem(s) studied
Improving syphilis screening and management in pregnant women

Interventions
The information from East Nusa Tenggara and Central Java will inform site selection and ensure balanced and buffered randomization of Puskesmas in a 1:1 ratio to either intervention or control (current practice) arms. The randomization will be conducted in STATA.

The intervention Puskesmas will receive targeted and enhanced support to promote the screening for and management of syphilis. The intervention has four components: i) Supply management system which will provide support to avoid delays in confirmatory testing and treatment initiation including optimisation of distribution and logistics, root cause analysis and implementation of standard operating procedures (SOPs) to strengthen inventory management systems. ii) Decision support tools including development and implementation of flow charts, SOPs and a supplementary syphilis birth plan (complete mother/baby pair record of syphilis management data) iii) Training of private and public midwives using a Training of trainers (ToT) programme that will be co-developed with the district health office and Puskesmas staff and implemented by the NGO partner to address hesitancy and lack of clarity about testing and treatment pathways for syphilis to iv) Education and awareness program which will include development of flyers, posters, infographics and animated videos that will be used to implement a facility-based of awareness program to raise awareness of early screening and treatment for syphilis.

The total duration of the intervention will be 12 months. In order to collect birth outcomes, both intervention and control arms will be followed up for an additional 6 months after the intervention has stopped.

Intervention Type
Behavioural

Primary outcome(s)
1. The proportion of women screened for syphilis during the first trimester is measured using secondary data reported in ANC registers and in the online surveillance systems at baseline, midline (6 months) and endline (12 months)
2. The proportion of women testing positive for syphilis who receive at least one dose of benzylpenicillin is measured using secondary data reported in ANC registers, in the online surveillance systems, and patient interviews, monthly including at endline (12 months)

Key secondary outcome(s))
1. The proportion of women with a positive syphilis test who are managed according to guidelines is measured using secondary data reported in ANC registers, and patient interviews at midpoint (6 months) and at endline (12 months).
2. The proportion of women testing positive for syphilis who complete treatment at least 30 days before delivery is measured using secondary data reported in ANC registers, and patient interviews at midpoint (6 months) and at endline (12 months).
3. The proportion of women testing positive with a birth plan at the time of delivery is measured using secondary data reported in ANC registers, and patient interviews at midpoint (6 months) and at endline (12 months).
4. Birth outcomes in women testing positive for syphilis, including spontaneous abortions, intrauterine fetal deaths, preterm birth or low birth weight, are measured using secondary data reported in ANC registers, and patient interviews at midpoint (6 months) and at endline (12 months).
5. The proportion of women tested for HIV in the first trimester is measured using secondary data reported in ANC registers, and patient interviews at midpoint (6 months) and at endline (12

months).
6. The proportion of women tested for HBV in the first trimester is measured using secondary data reported in ANC registers, and patient interviews at midpoint (6 months) and at endline (12 months).
7. The proportion of women tested for all three infections in the first trimester is measured using secondary data reported in ANC registers, and patient interviews at midpoint (6 months) and at endline (12 months).
8. The proportion of women tested for all three infections during pregnancy is measured using secondary data reported in ANC registers, and patient interviews at midpoint (6 months) and at endline (12 months).
9. The proportion of women testing positive for HIV who are started on ARV treatment within 2 weeks is measured using secondary data reported in ANC registers and patient interviews at midpoint (6 months) and at endline (12 months).
10. The total cost and cost-effectiveness of the intervention compared to standard care is measured using secondary data from project/facility/district financial accounts, patient diaries and time-in-motion studies at endline (12 months).
11. Uptake and acceptability of the multi-faceted intervention among key stakeholders is measured using stakeholder interviews at endline (12 months).

Completion date
30/09/2027

Eligibility

Key inclusion criteria
1. Facility eligibility: Eligible Puskesmas must:
1.1. Serve a mean of at least 320 new pregnant women per year, with
1.2. A burden of syphilis in pregnancy above the national average

2. Individual eligibility: All women attending their first ANC visit at participating Puskesmas or its network of community and private midwives, will be eligible to participate.

Participant type(s)
Patient, Health professional, Service user, Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
99 years

Sex
Female

Key exclusion criteria
Puskesmas participating in any interventions to promote syphilis detection and management

Date of first enrolment
01/03/2026

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
Indonesia

Study participating centre
Puskesmas in Central Java
Indonesia
Central Java

Study participating centre
Puskesmas in East Nusa Tenggara
Indonesia
East Nusa Tenggara

Sponsor information

Organisation
Universitas Gadjah Mada

ROR
https://ror.org/03ke6d638

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The project data will be deposited in the UK Data Archive and LSHTM Research Data Repository to make it accessible to other researchers in accordance with LSHTM Records Management Policy and MRC guidance. Sharing of the de-identified study data files will be permitted under strict data-sharing agreements and/or user registration. We will only share de-identified study data files. As part of the registration/data-sharing agreement process, users must agree to conditions including: 1) restrictions against attempting to identify participants, 2) commitment to securing the data using appropriate technology, 3) destruction of data after analyses are completed, 4) reporting responsibilities, 5) restrictions on redistribution of data, and 6) proper acknowledgement of the data source.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes