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A multicentre, double blind, placebo controlled, randomised trial to evaluate the effectiveness of a one-day versus seven-day regimen of nitrofurantoin for the treatment of asymptomatic bacteriuria in pregnancy

Submission date	Recruitment status	[_] Prospectively registered
14/12/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/12/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/12/2020	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
A35024

Study information

Scientific Title
A multicentre, double blind, placebo controlled, randomised trial to evaluate the effectiveness of a 1-day versus 7-day regimen of nitrofurantoin for the treatment of asymptomatic bacteriuria in pregnancy

Study objectives
Asymptomatic Bacteriuria (ASB) is defined as the presence of at least 100,000 colony forming units of a urinary pathogen per millilitre in a culture of a midstream urine specimen obtained from an asymptomatic woman on a routine scheduled visit. If this occurs in pregnant women, 20% to 30% of the untreated women may develop pyelonephritis. Of additional concern is the association of low birth weight and preterm delivery with untreated bacteriuria.

Hypothesis:
A one-day regimen of nitrofurantoin (100 mg twice a day) for asymptomatic bacteriuria in pregnant women is as effective as a seven-day regimen for the cure of the condition 14 days later than the first day of treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. World Health Organization (WHO) Ethics Review Committee (ERC) on the 24th November 2003
2. Ethics Committee of the Khon Kaen University on the 17th July 2003 (ref: HE460606)
3. Ethical Committee Ministry of Health Vietnam on the 24th April 2003
4. Ethics Review Board of the College of Medicine - University of the Philippines, Manila on the 28th October 2003

Study design
Randomised double blind placebo controlled clinical trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Asymptomatic Bacteriuria (ASB)

Interventions
Intervention: one-day regimen of nitrofurantoin (100 mg twice a day)
Control: seven-day regimen of nitrofurantoin (100 mg twice a day)

Contact details for Principal Investigator:
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Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Nitrofurantoin

Primary outcome measure
Bacteriological cure after the antibiotic treatment based on the result of midstream urine culture 14 days after the initiation of the treatment.

Secondary outcome measures
Incidences of:
1. Pyelonephritis
2. Preterm delivery
3. Low birth weight
4. Side effects

Overall study start date
01/03/2004

Completion date
01/03/2007

Eligibility

Key inclusion criteria

1. Pregnant women with gestational age 12 - 32 weeks
2. Willing and able to give consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
900

Total final enrolment
778

Key exclusion criteria
1. Have any underlying disease, which require continuous steroid and/or antibiotic treatment, e.g. systemic lupus erythematosus, valvular heart disease, etc.
2. Use of any antibiotics during the past one-week
3. Received any treatment for urinary tract infection at any time during the current pregnancy
4. History of nitrofurantoin hypersensitivity
5. Plan not to deliver at the study hospital
6. Any symptoms such as flank pain, dysuria that suggests symptomatic Urinary Tract Infections (UTI)
7. Have any haematological disease including Glucose-6-Phosphate Dehydrogenase deficiency (G6PD)
8. Negative urine dipslide
9. Negative urine culture
10. Positive urine culture but the organism is resistant to Nitrofurantoin

Date of first enrolment
01/03/2004

Date of final enrolment
01/03/2007

Locations

Countries of recruitment
Argentina

Philippines

Switzerland

Thailand

Viet Nam

Study participating centre
World Health Organization
Geneva-27
Switzerland
CH-1211

Sponsor information

Organisation
World Health Organization (WHO) (Switzerland)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.who.int/reproductive-health/

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
World Health Organization (WHO) (Switzerland) (ref: A35024)

Alternative Name(s)
, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2009	30/12/2020	Yes	No