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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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: Dr Pisake Lumbiganon Department of Obstetrics and Gynecology Faculty of Medicine Khon Kaen University Khon Kaen, 40002 Thailand

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Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Nitrofurantoin

Primary outcome(s)

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

Key secondary outcome(s))

Incidences of:

- 1. Pyelonephritis
- 2. Preterm delivery
- 3. Low birth weight
- 4. Side effects

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

778

Key exclusion criteria

- 1. Have any underlying disease, which require continuous steroid and/or antibiotic treatment, e. q. 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)

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, , BO3, OMS

Funding Body Type

Government organisation

Funding Body Subtype

International organizations

Location

Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

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