

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

☐ Prospectively registered

☐ Protocol

Registration date

14/12/2007

Overall study status

Completed

☐ Statistical analysis plan

☒ 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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Contact details

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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
Avenue Appia 20
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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