

A comparative study of the bactericidal and sterilising activity of three fluoroquinolones: gatifloxacin, moxifloxacin and ofloxacin substituted for ethambutol in the two month initial phase of the standard anti-tuberculosis treatment regimen also containing rifampicin, isoniazid and pyrazinamide (South Africa)

Submission date 07/04/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 07/06/2005	Overall study status Completed	☐ Protocol
Last Edited 26/03/2008	Condition category Infections and Infestations	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr T Kanyok

Contact details

20, Avenue Appia
Geneva -27
Switzerland
CH 1211
kanyokt@who.int

Additional identifiers

Protocol serial number

RPC078

Study information

Scientific Title

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Tuberculosis (TB)

Interventions

Control

Regimen 1: Standard TB treatment (isoniazid, rifampicin, pyrazinamide and ethambutol)

Interventions

Regimen 2: Isoniazid, rifampicin, pyrazinamide and gatifloxacin

Regimen 3: Isoniazid, rifampicin, pyrazinamide and ofloxacin

Regimen 4: Isoniazid, rifampicin, pyrazinamide and moxifloxacin

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Gatifloxacin, moxifloxacin and ofloxacin, ethambutol, rifampicin, isoniazid and pyrazinamide

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/01/2006

Eligibility

Key inclusion criteria

1. Male/female of 18-65 years
2. Weight 38-80 kg
3. Recently microscopically diagnosed pulmonary TB
4. Findings in medical history and physical examination not exceeding grade 2
5. Voluntarily signed informed consent
6. Confirmed negative pregnancy test at the screening visit
7. Willing to use effective contraceptive methods during treatment
8. Normal lab values not exceeding grade 2, except haemoglobin <6.5 g/dl and potassium <3.0 mEq/l (>grade 1)
9. Consent for a pre-screening biological test to exclude possible Multi Drug Resistant (MDR) TB and Negative MDR TB screen test will be a check if pre-screening biological test is done

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

Key exclusion criteria

1. History of TB within the last 3 years
2. Concomitant infection requiring additional anti-infectious treatment (especially anti-retroviral medication [ARV])
3. Human immunodeficiency virus (HIV) infected patients at World Health Organisation (WHO) stage 4
4. Diabetes mellitus or non insulin dependent diabetes mellitus requiring treatment
5. Drug and alcohol abuse
6. History of drug hypersensitivity and/or active allergic disease
7. Impaired renal, hepatic or gastric function that may interfere with drug absorption, distribution, metabolism or elimination

Date of first enrolment

25/11/2004

Date of final enrolment

01/01/2006

Locations**Countries of recruitment**

South Africa

Switzerland

Study participating centre

20, Avenue Appia

Geneva -27

Switzerland

CH 1211

Sponsor information**Organisation**

UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR)

ROR

<https://ror.org/01f80g185>

Funder(s)**Funder type**

Research organisation

Funder Name

United Nations Children's Fund (UNICEF)/United Nations Development Programme (UNDP) /World Bank/World Health Organization (WHO) - Special Programme for Research and Training in Tropical Diseases (TDR)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration