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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

Registration date
07/06/2005

Last Edited
26/03/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
25/11/2004

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Not provided at time of registration

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)

Sponsor details
20, Avenue Appia
Geneva -27
Switzerland
CH 1211

Sponsor type
Other

Website
http://www.who.int

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

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