# Levofloxacin versus ciprofloxacin combined with penicillin for the prevention of bacterial infections in neutropenic patients with haematological malignancies: a single centre, randomised clinical trial

Submission date	Recruitment status	Prospectively registered
20/12/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
20/12/2005	Completed	Results
Last Edited	Condition category	Individual participant data
19/12/2008	Haematological Disorders	Record updated in last yea

# 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

# Protocol serial number

**NTR341** 

# Study information

# Scientific Title

# **Study objectives**

Levofloxacin and the standard prophylaxis (ciprofloxacin and penicillin) are equivalent.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Received from the local medical ethics committee

# Study design

Randomised active controlled parallel group trial

# Primary study design

Interventional

# Study type(s)

Treatment

# Health condition(s) or problem(s) studied

Hemato-oncological patients, neutropenia

### **Interventions**

- 1. Conventional arm: ciprofloxacin 500 mg 2 x day and feniticilline 250 mg 4 x day
- 2. Experimental arm: levofloxacine 500 mg 1 x day

Both arms will be given from start chemotherapy until ANC recovery (greater than  $0.5 \times 10^{9}$ ).

# **Intervention Type**

Drug

### Phase

Not Applicable

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

Levofloxacin, ciprofloxacin, penicillin

# Primary outcome(s)

The number of microbiologically documented bacterial infections will be established

# Key secondary outcome(s))

- 1. The number of patients requiring initiation of empirical broad spectrum antibiotic therapy, time to infection, the number of antibiotics/antibiotic days will be established
- 2. The average values of these endpoints will be compared between the two treatment-groups

by means of Wilcoxon's Rank-sum test

3. Patients compliance and tolerability of the prophylactic regimen will be established from data of the patient questionnaire

# Completion date

01/09/2005

# **Eligibility**

# Key inclusion criteria

- 1. Men and women, aged 18 75 years
- 2. Patients admitted to the department of hematology for remission induction chemotherapy for acute leukaemia and other haematological malignancies
- 3. An anticipated granulocytopenic period of at least 10 days
- 4. Written informed consent

# Participant type(s)

Patient

# Healthy volunteers allowed

No

# Age group

Adult

# Lower age limit

18 years

# Upper age limit

75 years

### Sex

All

# Key exclusion criteria

- 1. A previous history of allergy to or known hypersensitivity to quinolone derivates or penicillin antibiotics
- 2. Fever within the preceding 24 hours
- 3. Infection requiring treatment at entry
- 4. Treatment with any antibiotics, within 48 hours prior to enrolment
- 5. Therapy with any other investigational drug during the preceding month
- 6. Concomitant experimental chemotherapy
- 7. Concomitant antibiotic therapy other than mentioned in the protocol
- 8. Known hepatic impairment as determined by elevation of any liver function test greater than three times the upper limit of normal, including: aspartate aminotransferase (ASAT), alanine aminotransferase (ALAT), lacate dehydrogenase (LDH), or alkaline phosphatase (AP), and serum bilirubin over 50 micromol/L
- 9. Creatinine clearance less than 15 ml/min
- 10. Patients with acquired immune deficiency syndrome (AIDS), AIDS-related complex (ARC) or known to be human immunodeficiency virus (HIV) positive

- 11. Pregnancy or lactation
- 12. World Health Organization (WHO) condition grade IV
- 13 .A history of alcoholism, drug abuse, psychosis, antagonistic personality, poor motivation or other emotional or intellectual problems that are likely to invalidate informed consent, or limit the ability of the subject to comply with the protocol requirements
- 14. Participation in other studies involving investigational products within one month prior to entry into this study or concomitantly with this study

## Date of first enrolment

15/01/2002

# Date of final enrolment

01/09/2005

# Locations

# Countries of recruitment

Netherlands

# Study participating centre Vrije University Medical Centre

Amsterdam Netherlands 1007 MB

# Sponsor information

# Organisation

Vrije University Medical Centre (VUMC) (The Netherlands)

### **ROR**

https://ror.org/00q6h8f30

# Funder(s)

# Funder type

Hospital/treatment centre

### **Funder Name**

Vrije University Medical Centre (VUMC) (The Netherlands) - Department of Haematology

# **Results and Publications**

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration