

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 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 19/12/2008	Condition category Haematological Disorders	☐ 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
Mr G.J. Timmers

Contact details
Vrije University Medical Centre
Department of Haematology
BR 240, P.O. Box 7057
Amsterdam
Netherlands
1007 MB
+31 (0)20 444 2604
gj.timmers@vumc.nl

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

Primary study design

Interventional

Study design

Randomised active controlled parallel group trial

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: levofloxacin 500 mg 1 x day

Both arms will be given from start chemotherapy until ANC recovery (greater than 0.5×10^9).

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 derivatives 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), lactate 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