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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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 19/12/2008	**Condition category** Haematological Disorders	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 x 10^9).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Levofloxacin, ciprofloxacin, penicillin

Primary outcome measure
The number of microbiologically documented bacterial infections will be established

Secondary outcome measures
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

Overall study start date
15/01/2002

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
245

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)

Sponsor details
Department of Haematology
P.O. Box 7057
Amsterdam
Netherlands
1007 MB

Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl

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

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