Levofloxacin versus ciprofloxacin combined with penicillin for the prevention of bacterial infections in neutropenic patients with hematological malignancies: a single center, randomized clinical trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21952

Source
NTR

Brief title
N/A

Health condition

Neutropenic patients with hematological malignancies.

Sponsors and support

Primary sponsor: Dept. of Hematology VUmc, Amsterdam, the Netherlands
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

The number of microbiologically documented bacterial infections will be established.

Secondary outcome

1. The number of patients requiring initiation of emperical broa spectrum antibiotic therapy, time to infection, the number of antibiotocs/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.

Study description

Background summary

Open label, single center, randomized clinical trial to evaluate the effectiveness of levofloxacin as prophylactic antibiotic regimen versus ciprofloxacin combined with penicilline in neutropenic patients with hematological malignancies.

Study objective

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

Study design

N/A

Intervention

Conventional arm:

ciprofloxacin 500mg 2x/day and feniticilline 250mg 4x/day

Experimental arm:

levofloxacine 500mg 1x/day.

Both arms will be given from start chemotherapy until ANC recovery (>0,5x109).

Contacts

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Eligibility criteria

Inclusion criteria

1. Men and women, aged 18-75 year;

2. Patients admitted to the department of hematology for remission induction chemotherapy for acute leukaemia and other hematological malignancies;

3. An anticipated granulocytopenic period of at least 10 days;

4. Written informed consent.

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, within48 hours prior to enrollment;

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:
ASAT,ALAT,lacate dehydrogenase (LDH), or alkaline phosphatase (AP), and serum bilirubin over 50 micromol/L;

9. A creatinin clearance <15ml/min;

10. Patients with AIDS, ARC or known to be HIV positive;

11. Pregnacy or lactation;

12. WHO condition grade IV;

13. A history of alcoholism, drug abuse, psychosis, antagonistic personality, poor motivation or other emational or intellectual problems that are likely to invalidate informed consent, or limit the ability of the subject to comply with the protocol requirments;

14. Participation in other studies involving investigational products within one month prior to entry into this study or concommitantly with this study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	15-01-2002
Enrollment:	245
Type:	Actual

Ethics review

Positive opinion Date:	12-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL303
NTR-old	NTR341
Other	: N/A
ISRCTN	ISRCTN68044984

Study results

Summary results
Clin Microbiol Infect. 2007 May;13(5):497-503. Epub 2007 Jan 30.