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

Gepubliceerd: 12-09-2005 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21952

Bron
NTR

Verkorte titel
N/A

Aandoening

Neutropenic patients with hematological malignancies.

Ondersteuning

Primaire sponsor: Dept. of Hematology VUmc, Amsterdam, the Netherlands
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The number of microbiologically documented bacterial infections will be established.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-01-2002
Aantal proefpersonen:	245
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

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