The influence of chloroquine-dosage as comedication on the response of "non-responder" dialysispatients at Hepatitis B vaccine

Published: 30-10-2006
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Study whether chloroquine as comedication results in a better respons on Hepatitis B vaccination in non-responder dialysis patients.

Ethical review	Approved WMO
Status	Pending
Health condition type	Immunodeficiency syndromes
Study type	Interventional

Summary

ID

NL-OMON29902

Source
ToetsingOnline

Brief title
The influence of chloroquine-admission on hepatitis B vaccine

Condition

- Immunodeficiency syndromes
- Nephropathies

Synonym
immunodeficiency, renal disease

Research involving
Human

Sponsors and support

Primary sponsor: Máxima Medisch Centrum

Source(s) of monetary or material Support: eigen budget

Intervention

Keyword: Chloroquine, Dialysis patients, Hepatitis B vaccination

Outcome measures

Primary outcome

Titre HbsAl in both arms

Secondary outcome

NA

Study description

Background summary

Chronic dialysis patients have a risk to viarale contamination by regular bloodcontact. The guidelines of the dutch dialysis and nefrology group avice to preventively vaccinate all dialysispatients for hepatitis B. In clinical pratice a lot of dialysispatients remain non-responder to the vaccination program. Resulting in a percentage of 20-30 of the dialysis patients not protected to a probable infection with Hepatitis B

Study objective

Study whether chloroquine as comedication results in a better respons on Hepatitis B vaccination in non-responder dialysis patients.

Study design

Prospective, randomized intervention-study

Intervention

10 patients receive on day 1 300 mg chloroquine and on day 3 an injection of Hbvaxpro
10 other patients receive on day 3 an injection of Hbvaxpro
At both arms after 2 weeks the titre HbsAl will be checked with 1 vial of blood of 5 ml

Study burden and risks

Burden tablet chloroquine: by mimimale dosage minimale side-effects
Burden Hepatitis B vaccination: Pain during intramusculair injection and this may cause haematoma.
Burden blood withdrawal: 5 ml of blood will be withdrawn out of a needle in situ

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Chronic hemodialysis patients,
Terminated Hepatitis B vaccination programme

Anti HbAl-titier < 10 IU/l

Exclusion criteria

Myasthenia Gravis,
Rethinopathia,
Hypersensitivity of 4-aminochinolinederivates

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Nivaquine®
Generic name:	Chloroquine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2006-001405-28-NL
CCMO	NL11587.000.06