Ribavirin: its dosing regime

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Is the area under the curve (AUC) of the dose ribavirin once daily equal to the AUC of a half dose twice daily?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON31511

Source
ToetsingOnline

Brief title
Ribados

Condition

- Viral infectious disorders

Synonym
Hepatitis C virus infection

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Hoffmann-La Roche

Intervention

Keyword: Dosis frequency, Pharmacokinetics, Ribavirin

Outcome measures

Primary outcome

The pharmacokinetics of ribavirin at different dosage regimes, measured by the area under the curve of the concentration-time graph.

Secondary outcome

-The tolerability of the treatment at different dosage regimes of ribavirin.

-Is the antioxidant capacity in plasma and erythrocytes different for the dosing regimes?

-What is the effect of ribavirin on the hemolysis?

-What is the antioxidant acitivity of ribavirin?

-What is the pharmacokinetics of ribavirin in the different dosing regimes in erythrocytes?

Study description

Background summary

The standard treatment of patients with chronic hepatitis C virus infection (HCV) is treatment with ribavirin. Actually, the compliance (2x daily) seems to be a problem. To increase patients' compliance, it is investigated if the total dose of ribavirin can be taken once daily.

Study objective

Is the area under the curve (AUC) of the dose ribavirin once daily equal to the AUC of a half dose twice daily?

Study design

Randomized, cross-over, parallel group.

Intervention

One group starts with a half dose ribavirin twice daily and after 12 weeks the total dose once daily.
The second group starts with the total dose ribavirin once daily and after 12 weeks the half dose twice daily.

Study burden and risks

In addition to the standard treatment, bloodsamples are taken at two different days. The risk is minimal.
The dosing regime of ribavirin is once daily instead of twice daily (the half dose). The risk is minimal.

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

According to standard treatment of HCV with ribavirin. Additional for this study:
-Obtained written informed consent
-Age above 18 years
-Body weight >=70 kg: At a lower body weight, a dose of ribavirin is used (400/600mg a day) that cannot be used in this study.;Main inclusion criteria for standard treatment are:
Anti-HCV positivity >6 months
Positive HCV-RNA genotype 1 or 4
Liver biopsy within one year before start of treatment
intention to be treated and participate treatment

Exclusion criteria

Main exclusioncriteria for the standard treatment are:
Pregnancy or intention to get pregnant within the treatment period + 6 months
no adequate contraception (for men and women)
HIV positivity
Active uncontrolled psychiatric disorders and suicidal leanings
patients with a history of uncontrolled seizure or other significant CNS dysfunction
Chemotherapy, systemic antiviral treatment during 6 months prior to study entry
Other serious disease

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	05-07-2007
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Copegus
Generic name:	ribavirin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	19-04-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-04-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-01-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-01-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-08-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2006-003404-19-NL
CCMO	NL12978.068.07