A Single dose, two-way crossover study of the bioequivalence of two formulations of Ribavirin

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To assess the bioequivalence of two marketed formulations of ribavirin (ribavirin solution and capsules).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON36756

Source
ToetsingOnline

Brief title
BE of Ribavirin

Condition

- Hepatic and hepatobiliary disorders

Synonym
Hepatitis C

Research involving
Human

Sponsors and support

Primary sponsor: Schering-Plough
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: Bioequivalence, Hepatitis C

Outcome measures

Primary outcome

Pharmacokinetics

Safety

Secondary outcome

N/A

Study description

Background summary

The drug to be given, Ribavirin is registered for the treatment of chronic hepatitis C virus (HCV) as part of a combination therapy with two other medications (peginterferon alfa-2b or interferon alfa-2b) registered for the treatment of hepatitis C and part of the standard-of-care treatment. Hepatitis C is an infectious disease affecting the liver and is spread by blood-to-blood contact.
Ribavirin is approved as capsules containing 200 mg of ribavirin or as a solution for pediatric use containing 40 mg/mL ribavirin. In this study we want to confirm that both formulations are essentially the same in their effects, efficacy and safety.

Study objective

To assess the bioequivalence of two marketed formulations of ribavirin (ribavirin solution and capsules).

Study design

Design:
An open-label, randomized, two-way crossover bioequivalence study in fifty four healthy male and/or healthy female (postmenopausal/sterilized) subjects receiving a single oral dose of ribavirin as oral solution in one period and a single oral dose of ribavirin as capsules in the other period; a washout of at least five weeks between dosing

Screening and follow-up:
Clinical laboratory, vital signs (including oral temperature), physical examination, weight, 12-lead ECG; at eligibility screening: medical history, height, elbow breadth measurement, drug screen, E2 and FSH (PM females only), HBsAg, anti HCV, anti-HIV 1/2 and pregnancy test (surgically sterile females only); follow-up at discharge from clinic in Period 2; physical examination, drug screen, clinical laboratory and vital signs (including oral temperature) to be repeated upon admission Period 1; pregnancy test (surgically sterile females only).

Observation period:
2 periods, each period in clinic from -17 h up to 72 h after drug administration

Blood sampling:
Por pharmacokinetics of ribavirin in plasma: pre-dose and at 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 12, 14, 24, 36, 48, and 72 hours post dose Day 1.
for genotyping: pre-dose (first period only)

Safety assessments:
Adverse events: throughout the study; weight: pre-dose; vital signs (including oral temperature): pre-dose and once on Day 4;

Bioanalysis:
Analysis of plasma ribavirin samples using a validated method by Sponsor

Intervention

Active substance: ribavirin

Study burden and risks

Procedures: pain, light bleeding, heamatoma and possibly an infection.

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

18-55 years,
BMI 18-30 kg/m2 (inclusive)
man or postmenopausal women

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/Aids. In case of participation in another drug study within 60 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood (for men) / more than 1.0 liters of blood (for women) in the 10 months preceding the start of this study.

Study design

Design

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):	10-05-2011
Enrollment:	54
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ribavirin
Generic name:	Rebetol
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2010-018731-17-NL
CCMO	NL31493.056.10