A Phase I, open-label, randomized, 2-way crossover trial in 2 parallel panels of 20 healthy subjects each to investigate the pharmacokinetic interaction between lopinavir/ritonavir (LPV/rtv) and telaprevir, and between atazanavir/ritonavir (ATV/rtv) and telaprevir, all at steady-state.

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The first aim of the study is to investigate the effect of telaprevir on the concentration of LPV/rtv and ATV/rtv in the blood and the effect of LPV/rtv and of ATV/rtv the concentration of telaprevir in the blood.The second aim is to investigate the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON30839

Source
ToetsingOnline

Brief title
An interaction study of telaprevir in combination with LPV/rtv or ATV/rtv

Condition

- Viral infectious disorders

Synonym
hepatitis C / liver disease

Research involving
Human

Sponsors and support

Primary sponsor: Tibotec Pharmaceuticals
Source(s) of monetary or material Support: bedrijf: Tibotec BVBA

Intervention

Keyword: healthy subjects, hepatitis C, metabolic interaction, telaprevir

Outcome measures

Primary outcome

The first aim of the study is to investigate the effect of telaprevir on the

voncentration of LPV/rtv and ATV/rtv in the blood and the effect of LPV/rtv

and ATV/rtv on the concentration telaprevir in the blood.

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Secondary outcome

The second aim is to investigate the safety and toleribility of the

coadministartion of telaprevir and LPV/rtv and ATV/rtv in healthy volunteers.

Study description

Background summary

The investigational drug telaprevir is being developed in order to be used in the future to treat patients with Hepatitis C. Telaprevir is not approved by the US Food and Drug administration and other European governmental department. This explains why the investigational product can only be used in this trial.

Up to now, telaprevir has been given to approximately 300 healthy volunteers and moreover than 600 Hepatitis C patients within a finished or ongoing trial.

Telaprevir belong to the group of antivirals, which can be used in combination with other registered medication for the treatment of Hepatitis C. Lopinavir (LPV) and atazanavir (ATV) are prescribed medication used for the treatment of HIV (human immunodeficiency virus). This medication will be given in low doses and always in combination with a low dose ritonavir (rtv).

The comedication with ritonavir leads to a better concentration of LPV and ATV in the blood and to a better tolerability of this medicines. The aim of this study is to obtain more information about the recommended dose for the comedication of these medicines to treat patients with both Hepatitis C and HIV.

Study objective

The first aim of the study is to investigate the effect of telaprevir on the concentration of LPV/rtv and ATV/rtv in the blood and the effect of LPV/rtv and of ATV/rtv the concentration of telaprevir in the blood.
The second aim is to investigate the safety and toleribility of the coadministration of telaprevir and LPV/rtv and ATV/rtv in healthy volunteers.

Study design

Two panels of 20 healthy male and female volunteers will be participating in this trial. The study will consist of a screening and two parts per panel. One of the parts will consist of an admission of 3 days and 2 short visits. The other part will consist of an admission 4 of days, an admission of 7 or 8 days and 3 short visits. Finally there will be 2 follow ups. There will be a period of minimal 13 days between the two parts.
Volunteers in panel 1 will receive treatments A&BB. Volunteers in panel 2 will receive treatments C&D. The order of treatments in a panel will be based on chance.

Treatment A, Panel 1:
- 750 mg telaprevir every 8 hours from Day 1 to Day 9 and a morning dose on Day 10.
Treatment B, Panel 1:
- 400/100 mg LPV/rtv twice daily from Day 1 to Day 23 and a morning dose on Day 24.
- 750 mg telaprevir every 8 hours from Day 11 to Day 20 and 750 mg telaprevir every 12 hours from Day 21 to Day 23 and a morning dose on Day 24.
Treatment C, Panel 2:
- 750 mg telaprevir every 8 hours from Day 1 to Day 9 and a morning dose on Day 10.
Treatment D, Panel 2:
- 300/100 mg ATV/rtv once daily from Day 1 to Day 24
- 750 mg telaprevir every 8 hours from Day 11 to Day 20 and 750 mg telaprevir

every 12 hours from Day 21 to Day 24

Study burden and risks

The risks of participation in this trial is associated with possible adverse events of telaprevir, LPV/rtv and ATV/rtv. The burden for the participant is also associated with the admission to the unit, venapunction and insertion of canule. All subjects will be carefully followed on any adverse events and will be under the supervision of experienced physicians and study personnel.

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

1. Permission in writing from volunteer to participate in this trial
2. Age 18-55 years
3. In good physical and mental health
4. Normal weight length ratio (BMI 18-30 kg/m2);
5. Women should be postmenopausal for at least 2 years, or have undergone a hysterectomy, or have had a tubal ligation (without reversal operation)
6. No significant abnormalities will be found at screening
7. Non smoking or smoking no more than 10 cigarettes, or 2 cigars, or 2 pipes per day for at least 3 months before study screening

Exclusion criteria

1. History of alcohol or drug abuse within 2 years prior to dosing
2. Eye disorder at admission
3. Current or past relevant disease concerning the cardio vascular system, respiratory system, kidneys, liver, blood, hormone system, nervous system, immunological system, skin or psychiatric condition
4. Having an illness within 5 day prior to receiving the first dose of study medication, e.g. nausea, vomiting, flu,
5. In the opinion of the physician any relevant abnormality on your ECG
6. Any medical condition which is of influence on the absorption, distribution, metabolism and excretion of the study medication
7. Use of over the counter drugs within 14 day of dosing, including herbal supplements (except for paracetamol and vitamins)
8. Use of prescription medication within 30 days before dosing
9. Have had an relevant allergic reaction on medication
10. Use of grapefruit or grapefruit containing, alcohol, caffeine containing products
11. products 48 hours before admission
12. Participation in a clinical trial within 2 months before dosing
13. Donation of blood within three months before dosing
14. Hepatitis B, C or HIV positive
15. If in the opinion of the physician the volunteer is not suitable to participate in this trial.

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-10-2007
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Kaletra
Generic name:	lopinavir/ritonavir
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	NA
Generic name:	telaprevir
Product type:	Medicine
Brand name:	Norvir
Generic name:	ritanovir
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Reyataz
Generic name:	atazanavir
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	31-07-2007
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	22-08-2007

Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	07-09-2007
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	16-11-2007
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	EUCTR2007-003547-79-NL
CCMO	NL18745.072.07