AN OPEN-LABEL, SINGLE CENTRE TRIAL TO INVESTIGATE THE MASS BALANCE AND METABOLITE PROFILE OF A SINGLE ORAL DOSE OF AIC090019

Published: 20-09-2010
Last updated: 04-05-2024

Primary:To evaluate the mass balance of the study medicationTo identify the metabolites of the study medication in plasma and excreta (urine and faeces)To identify the routes of elimination of the study medication in humansSecondary To assess the...

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

Summary

ID

NL-OMON34410

Source
ToetsingOnline

Brief title
AIC090019 mass balance/Met-ID trial

Condition

- Viral infectious disorders

Synonym
Hepatitis B, viral infection

Research involving
Human

Sponsors and support

Primary sponsor: AiCuris GmbH & Co. KG

Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: AIC090019, Hepatitis B

Outcome measures

Primary outcome

- Radiokinetics

- Pharmacokinetics

- Safety

Secondary outcome

n.a.

Study description

Background summary

The drug to be given is a new investigational compound that may eventually be used for the treatment of hepatitis B. Chronic hepatitis B virus (HBV) infection remains a major cause of severe liver disease and premature liver-related mortality, worldwide. Epidemiologic trials (trial of factors affecting the health and illness of populations) have indicated that 350 to 400 million persons are infected. 15 to 40% of these infected persons are at risk for premature mortality from complications of the infection such as liver failure and liver cancer.
There are presently seven medications for the treatment of hepatitis B available. These medications suppress the virus. The treatment is, however, not always successful and some of these medications have severe side effects.
It is expected that the compound contributes to the treatment of patients with chronic hepatitis by suppressing the virus and, potentially, decreasing the virus.

Study objective

Primary:
To evaluate the mass balance of the study medication
To identify the metabolites of the study medication in plasma and excreta

(urine and faeces)
To identify the routes of elimination of the study medication in humans

Secondary
To assess the safety and tolerability of the study medication
To determine the profile of the study medication and its metabolites in humans in plasma and excreta (urine and faeces)

Study design

Design:
This is an open-label, single centre, absorption, distribution, metabolism and excretion (ADME) trial in 8 healthy male subjects. Subjects will receive 50 mg unlabeled study medi as an oral solution in the morning of Day 1 spiked with an oral solution containing a tracer dose of 20 kBq of radio labeled study medication.

Procedures and assessments
Screening and follow-up:
Clinical laboratory examination (including clinical chemistry, haematology, coagulation and urinalysis), physical examination (including body weight), vital signs (including supine systolic and diastolic blood pressure, pulse rate and oral body temperature), 12 lead electrocardiogram (ECG) and previous and concomitant medication

Screening:
Demographics, body height, medical history and concomitant diseases, drug and alcohol screen, HBsAg, anti-HBc, anti HCV and anti-HIV 1/2

Admission:
Oral body temperature, drug and alcohol screen, adverse events (AEs), and previous and concomitant medication

Observation period:
One period in clinic from -18 h up to 168 h (Day 8) after drug administration, there will be a follow-up visit 14-21 days after dosing

Blood sampling:
For pharmacokinetics (PK) of the study medication and total radioactivity in plasma: at pre-dose and 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 7, 8, 10, 12, 16, 24, 36, 48, 72, 96, 120, 144 and 168 hours post-dose
For metabolite identification: at 0.5, 1, 3, 6, 12, 24, 48, 72, 96, 120, 144 and 168 hours post-dose
For pharmacogenetics: pre-dose

Urine sampling:
For PK of total radioactivity and metabolite identification: at pre-dose and 0

4, 4-8, 8 12, 12-24, 24-48, 48-72, 72-96, 96-120, 120-144 and 144-168 hours post-dose

Faeces sampling:
For PK of total radioactivity and metabolite identification: at pre-dose and 0 12, 12-24, 24 48, 48-72, 72-96, 96-120, 120-144 and 144-168 hours post-dose

Safety assessments:
AEs: recorded from admission until completion of the follow up visit and specifically within 1 hour pre-dose and at 1, 2, 4, 12, 24, 48, 72, 96, 120, 144 and 168 hours post-dose; clinical laboratory examinations (including clinical chemistry, haematology, coagulation and urinalysis): on Day -1 and at 168 hours post-dose; vital signs (including supine systolic and diastolic blood pressure and pulse rate) and 12 lead ECG: within 1 hour pre-dose and at 1, 2, 4, 12, 24, 48, 72, 96, 120, 144 and 168 hours post-dose; physical examination: at 168 hours post-dose

Bioanalysis:
analysis of plasma, urine and faeces samples using validated methods by Sponsor
analysis of total radioactivity in plasma, urine and faeces using validated methods by Sponsor
metabolite identification by Sponsor
genotyping by Sponsor

Intervention

Active substance: AIC090019 and [14C]-AIC090019

Study burden and risks

Procedures: pain, light bleeding, heamatoma, possibly an infection.
One serious adverse reaction was reported: erosive gastritis in one subject who received 50 mg. This event was considered to be mild in intensity and assessed as possibly related to the trial medication. This was treated (including prolonged hospitalisation) and during the post-trial examination performed on Day 14 post dose the subject did not show any clinical findings.

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

- Healthy male
- 18-45 years of age, inclusive
- BMI 18.0-28.0 kg/m2
- Non-smoker or light to moderate smoker

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 (50 mL or more) within 60 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study. Participation is also not permitted when participated in more than 3 other drug studies in the 10 months prior to the start of this study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2010
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO Date:	20-09-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-09-2010
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	EUCTR2010-022250-17-NL
CCMO	NL33751.056.10