PLASMA CONCENTRATION, EXCRETION AND MASS BALANCE OF ORALLY ADMINISTERED 14C-FYX-051 IN HEALTHY MALE SUBJECTS

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Purine and pyrimidine metabolism disorders
Study type	Interventional

Summary

ID

NL-OMON34440

Source
ToetsingOnline

Brief title
14C-FYX-051 ADME STUDY

Condition

- Purine and pyrimidine metabolism disorders
- Joint disorders

Synonym
Gout, Hyperuricemia

Research involving
Human

Sponsors and support

Primary sponsor: Fuji Yakuhin Co.,Ltd.
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: FYX-051, Gout, Hyperuricemia

Outcome measures

Primary outcome

To assess the pharmacokinetics, metabolism, and routes and extent of

elimination, and to identify the metabolites of FYX-051 after a single 80 mg

oral dose of 14C-FYX-051 in healthy male subjects

To characterize the exposure to and the elimination of the metabolites of

FX-051 in healthy male subjects

Secondary outcome

To assess the safety of a single oral 80-mg dose of 14C-FYX-051

Study description

Background summary

The drug to be given, FYX-051 is a new, investigational compound that may eventually be used for the treatment of gout. Gout can present itself in a number of ways, although the most common is a recurrent attack of acute inflammation of joints. Gout is caused by abnormal high levels of uric acid in the blood. In order to prevent reoccurrence of gout, patients are treated with a drug that controls uric acid concentrations in the blood. The drugs that are currently used for clinical treatment are known to cause serious side effects, such as liver problems. Others are safe, however they can be difficult to use and less effective.
FYX-051 is a new type of drug that has a two-fold working mechanism: it inhibits two different enzymes involved in the production of uric acid.
FYX-051 is expected to cause less side effects and is a more potent drug than

the drugs that are currently used.

Study objective

The purpose of the study is to investigate how quickly and to what extent FYX-051 is absorbed, distributed, metabolized (converted) and eliminated from the body. The compound to be administered will be labeled with 14-Carbon (14C) and is thus radioactive. This enables the investigator to trace the compound in blood, exhaled air, urine and feces. The safety of the compound will also be evaluated.

Study design

Design:
This is a Phase I, open-label, non-randomised, single centre absorption, distribution, metabolism and excretion (ADME) study in 6 healthy male subjects who will all receive a single oral dose of 80 mg FYX-051 containing 3.7 MBq (0.6 mSv) of 14C FYX-051.

Procedures and assessments
Screening and end-of-study visit:
clinical laboratory (including clinical chemistry, haematology and urinalysis), physical examination, vital signs (including supine systolic and diastolic blood pressure and pulse rate), 12 lead electrocardiogram (ECG).
Screening: demographics, body weight and height, medical history, drug and alcohol screen, HBsAg, anti HCV and anti HIV 1/2
Admission: physical examination, drug and alcohol screen, adverse events (AEs).

Blood sampling:
for total radioactivity in plasma and whole blood: pre-dose and 0.25, 0.5, 1, 2, 4, 8, 12, 24, 48, 72, 96, 120, 144 and 168 h post-dose and each 24 h in case of prolonged in-house stay
for hematocrit measurement in whole blood: pre-dose, 0.5, 24 and 48 h post-dose
for FYX-051 and its metabolites in plasma : pre-dose and 0.25, 0.5, 1, 2, 4, 8, 12, 24, 48, 72, 96, 120, 144 and 168 h post-dose (The time points of 48 h post-dose would not be analyzed for FYX-051 and metabolites when the total radioactivities in these points are quite low.) .
Metabolic profiling in plasma: 1, 4, 8 and 24 h post-dose

Urine sampling:
for total radioactivity, FYX-051 and its metabolites, and metabolite profiling: pre-dose and 0-6, 6-12 and 12-24 h post-dose and then every 24 h interval until criteria are met (The time points of after 48 h post-dose would not be analyzed for FYX-051 and metabolites when the total radioactivities in these points are quite low.).

Feces sampling:
for total radioactivity, FYX-051 and its metabolites, and metabolite profiling: pre-dose and then every 24 h interval after drug administration until criteria are met (The time points of after 48 h post-dose would not be analyzed for FYX-051 and metabolites when the total radioactivities in these points are quite low.).

Expired air sampling:
for total radioactivity: pre-dose (baseline) and 0.5, 4, 12, 24, 48, 72 and 96 h post-dose

Safety assessments:
AEs: throughout the study; 12-lead ECG: pre-dose and at 2, 8 and 24 h post-dose and end-of-study visit; vital signs: pre dose and at 2, 4, 8 and 12 h post-dose and once daily on Days 2-8; physical examination on Day -1 (pre-dose), Day 1 post-dose and on Day 5.

Bioanalysis:
analysis of plasma, feces and urine samples for FYX-051 and its metabolites using radio-HPLC method by Sekisui Medical;
analysis of total radioactivity in whole blood, plasma, urine, feces and expired air using a validated method by PRA
metabolic profiling by Sekisui Medical
quick counts by PRA

Intervention

Active compound: 14C enriched FYX-051, 80 mg FYX-051, 3,7 MBq (0,6 mSv) as an oral suspension (2 mg/ml)

Study burden and risks

Procedures: pain, light bleeding, heamatoma, possibly an infection,
The following adverse effects were reported during previous studies: nausea, feeling hot and diarrhea.

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
- you are between 20 and 35 years of age;
- your BMI is between 18.0 and 30.0 kg/m2 (to calculate your BMI (Body Mass Index): divide your weight (in kg) by your squared length in meters (weight / (length x length));
- you do not smoke or are a moderate smoker (please note that during your stay in the clinical research centre and in the 48h-period prior to your stay, smoking is not allowed)

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 90 days from the start of the study. In case of donating more than 1.5 liters of blood in the 12 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):	04-10-2010
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	21-09-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-09-2010
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	EUCTR2010-021958-19-NL
CCMO	NL33776.056.10