An Open Label, Non-Randomized, Single dose, Mass Balance Study to Investigate the Recovery, Excretion, and Pharmacokinetics of 14C-GSK2251052 Administered as a Single Intravenous Dose to Healthy Adult Subjects (LRS115243)

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

Summary

ID

NL-OMON36141

Source
ToetsingOnline

Brief title
[14C]-GSK2251052 mass balance study

Condition

- Bacterial infectious disorders

Synonym
Bacterial infections

Research involving
Human

Sponsors and support

Primary sponsor: GlaxoSmithKline
Source(s) of monetary or material Support: Farmaceutische Industrie

Intervention

Keyword: [14C]-GSK2251052, ADME, bacterial infections

Outcome measures

Primary outcome

- radiokinetics

- pharmacokinetics

- safety

- tolerability

Secondary outcome

na

Study description

Background summary

The drug to be given GSK2251052 is a new, investigational compound that may eventually be used for the treatment of bacterial infections.
Bacteria are getting more and more immune to currently available antibiotics. Thus there is a need for new drugs that can serve as antibiotics. Of GSK2251052 is expected that it stops the growth of bacteria by inhibiting the synthesis of proteins the bacteria need to grow.

Study objective

The purpose of the study is to investigate how quickly and to what extent GSK2251052 is absorbed, distributed, metabolized (converted) and eliminated from the body (this is called pharmacokinetics). 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, urine and feces. The safety and tolerability of the compound will also be evaluated.

Study design

Design:
open-label, non-randomized, mass-balance study in six healthy male subjects receiving a single one hour iv infusion of [14C]-GSK2251052, containing approximately 0.56 MBq

Screening and follow up:
clinical laboratory, vital signs, physical examination, ECG (in triplicate at screening); at eligibility screening: medical history, urine and alcohol and drug screen, HBsAg, anti HCV, anti-HIV 1/2; ECG (in triplicate), urine alcohol and drug screen, vital signs and clinical laboratory to be repeated upon admission.

Observarion period:
one period in clinic from -17 h up to 336 h (Day 15) after drug administration if total radioactivity in 2 consecutive 24-hour collections (288-312 hours post-dose [Days 12-13] and 312-336 hours [Days 13-14] post-dose) in both urine and faeces combined are * 1% of the administered dose. In the event that total radioactivity in faeces and/or urine is >1% of the administered dose at 336 hours, subjects will be required to return to the unit every 168 hours (7 days) or until the radioactivity excreted falls to *1% of the administered dose .

Blood sampling:
for pharmacokinetics of GSK2251051, metabolic profiling in plasma and total radioactivity in plasma and whole blood: pre-dose prior to the start of infusion, 0.5, 1 (just prior to the end of infusion) and 5, 15, 30 minutes and 2, 3, 4, 5, 6, 8, 12, 16, 24, 36, 48, 60, 72, 96, 120, 144, 168 and 192 hours post-dose.

Urine sampling:
for pharmacokinetics of GSK2251051, total radioactivity and metabolic profiling: pre-dose and intervals 0-6, 6-12, 12-24 and 24 h intervals up to discharge

Feces sampling:
for pharmacokinetics of GSK2251051, total radioactivity and metabolic profiling: pre-dose and 0-24 and 24 h intervals up to discharge

Safety assessments
adverse events: throughout the study; ECG: pre-dose, immediately after the end of the infusion, 1 and 24 h after the end of infusion and once on Day 15; vital signs: pre-dose (2x) and once on Day 15; clinical laboratory: once on Days 1, 2

and 15; physical examination: once on Day 15

Bioanalysis:
analysis of plasma, urine and faeces analysis of plasma, urine and faeces GSK2251051 samples using validated methods by Sponsor
analysis of total radioactivity in plasma, urine, whole blood and faeces using validated methods by PRA
metabolic profiling by Sponsor

Intervention

active substance: GSK2251052 and [14C]-GSK2251052

Study burden and risks

Procedures: pain, licht bleeding, bruses, possible infection.

A single dose of GSK2251052 as an injection has been given to 32 healthy volunteers and as a pill to 18 healthy volunteers. Multiple doses of GSK2251052 have been given as an injection to 40 healthy volunteers and as a pill to 9 healthy volunteers.
The most common reported side effects after single or multiple intravenous doses of GSK2251052 were drop in blood pressure upon standing, diarrhea, headache, sore chest muscles, feeling tired, abnormal heartbeat, dizziness and nausea. There were also changes observed in some lab results including red blood cells, reticulocytes (*young* red blood cells), and liver tests after multiple doses of GSK2251052 were given. However, these changes were not associated directly with signs or symptoms and lab results returned to normal after dosing stopped. Your blood will be taken multiple times during this study to look for this effect after your injected dose.

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 subjects
Age: 30-55 years
BMI: 18.5-30.0 kg/m2

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 or in case of donating more than 1 liter of blood in the 10 months prior 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):	08-04-2011
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	15-03-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-03-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-04-2011
Application type:	Amendment
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	EUCTR2010-024205-13-NL
CCMO	NL35805.056.11