An open-label, two period study to determine the excretion balance and pharmacokinetics of 14C-GSK573719, administered as single dose of an oral solution and an intravenous infusion, to healthy male adults

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON36078

Source
ToetsingOnline

Brief title
14C-GSK573719 ADME study

Condition

- Respiratory tract infections

Synonym
asthma, COPD

Research involving

Human

Sponsors and support

Primary sponsor: GlaxoSmithKline
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: ADME, COPD, GSK573719

Outcome measures

Primary outcome

- radiokinetics

- pharmacokinetics

- safety

- tolerability

Secondary outcome

na

Study description

Background summary

GSK573719 is a new investigational compound that may eventually be used for the treatment of Chronic Obstructive Pulmonary Disease (COPD). GSK573719 is not registered as a drug but has been given to humans before.

Study objective

The purpose of the study is to investigate how quickly and to what extent GSK573719 is absorbed, distributed, metabolized (broken down) 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, bile, urine and faeces. The safety and tolerability of the compound will also be evaluated.

Study design

Design:
an open-label, two-period, single-dose ADME study in six healthy male subjects each receiving a single intravenous infusion dose of [14C]-GSK573719 administered over 30 minutes in the first dosing period and a single oral dose of [14C]-GSK573719 in the second dosing period with a washout of at least 28 days between doses.

Screening and follow up:
clinical laboratory, physical examination, ECG, vital signs; at eligibility screening: medical history, alcohol urine test, drug screen, HBsAg, anti HCV, anti-HIV 1/2, urine cotinine, pharmacokinetic blood sample; brief physical examination, alcohol urine test, drug screen and clinical laboratory to be repeated upon each admission

Observation period:
two periods in clinic from -17 h up to 168 h after drug administration with a possible extension to Day 11, subjects can be discharged if 1% or less of the dose is excreted in a 24 h on Day 6 and Day 7; feaces collection may continue at home up to Day 14

Blood sampling:
for pharmacokinetics of GSK573719 and metabolites: pre-dose on Day -1, pre-dose and 0.5, 0.75, 1, 2, 3, 4, 6, 8, 12, 24, 48, 96 and 168 h post-dose
for total radioactivity and metabolite profiling: pre-dose and 0.75, 1, 3, 6 and 24 h post-dose

Urine sampling:
for pharmacokinetics and total radioactivity: pre-dose and intervals 0-24, 24-48, 48-72, 72-96, 96-120, 120-144, 144-168 h post-dose (one aliquot of each urine collection will be taken for metabolite profiling); urine collection may continue until Day 11

Feces collection:
for pharmacokinetics and total radioactivity: pre-dose and intervals 0-24, 24-48, 48-72, 72-96, 96-120, 120-144, 144-168 h post-dose (one aliquot of each faeces collection will be taken for metabolite profiling); faeces collection may continue until Day 14

Bile sampling:
entero test: in the fasted state from 3.5 h pre-dose until approximately 2.5 h post-dose on Day 1 in treatment Period 2

Safety assessments:
adverse events: throughout the study; vital signs and ECG: pre-dose and 0.5, 1,

2, 6 and 12 h post-dose

Bioanalysis:
analysis of plasma GSK573719 samples using validated methods by PRA
analysis of total radioactivity in plasma, urine and faeces using validated methods by PRA
metabolite profiling by Sponsor
analysis of bile samples by Sponsor

Intervention

active substance: GSK573719 and [14C]-GSK573719

Study burden and risks

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

In previous studies a total of 182 healthy volunteers have received single and multiple (up to 14 days) dose administrations of GSK573719 up to 1.0 mg daily. The most important adverse events reported were: headache, coughing, dry mouth and strange taste.

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
non smokers
Age: 30-55 years
BMI: 18.5-29.0 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):	29-04-2011
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	31-03-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-04-2011
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	EUCTR2010-024564-17-NL
CCMO	NL36214.056.11