A randomised, double-blind, placebo-controlled, cross-over study to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of single ascending oral doses of GSK2239633 in healthy male subjects.

Published: 15-03-2011
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Primary:*To assess the safety and tolerability of single ascending oral doses of GSK2239633 in healthy male subjects. Secondary*To assess the pharmacokinetics of GSK2239633 following single ascending oral doses in healthy male subjects. * To assess...

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

Summary

ID

NL-OMON36158

Source
ToetsingOnline

Brief title
GSK2239633 SAD study

Condition

- Respiratory tract infections

Synonym
Asthma, fungal infection of the lungs

Research involving

Human

Sponsors and support

Primary sponsor: PRA International EDS
Source(s) of monetary or material Support: GlaxoSmithKline Research & Development Limited Brentford Middlesex UK

Intervention

Keyword: asthma and allergic bronchopulmonary aspergillosis, GSK2239633

Outcome measures

Primary outcome

Adverse events

Clinically relevant changes in safety parameters: 12-lead ECG, telemetry, vital signs (systolic and diastolic blood pressure, heart rate, temperature), clinical laboratory data (haematology, clinical chemistry, urinalysis).

Secondary outcome

Derived pharmacokinetic parameters for GSK2239633 including area under the plasma drug concentration versus time curve (AUC(0-t), AUC(0-)), maximum observed plasma drug concentration (Cmax), time to maximum observed plasma drug concentration (tmax), apparent clearance (CL/F) and terminal half-life (t1/2) following single oral doses.

*Pharmacodynamic inhibitory effect of GSK2239633 on CCR4-mediated T cell actin polymerisation in whole blood.

Study description

Background summary

The drug to be given is a new investigational compound that may eventually be used for the treatment of asthma and allergic bronchopulmonary aspergillosis. It is a chemokine receptor 4 (CCR4) antagonist, a compound which is thought to inactivate the part of the immune system that is involved in diseases like asthma and allergic bronchopulmonary aspergillosis.

Study objective

Primary:
*To assess the safety and tolerability of single ascending oral doses of GSK2239633 in healthy male subjects.

Secondary
*To assess the pharmacokinetics of GSK2239633 following single ascending oral doses in healthy male subjects.
* To assess the relationship between pharmacokinetics and pharmacodynamics of GSK2239633 following single ascending oral doses of GSK2239633 in healthy male subjects.
* To assess the effect of food on the pharmacokinetics of GSK2239633 following single oral doses of GSK2239633 in healthy male subjects.

Study design

This study will be performed in 24 healthy male subjects.
Group 1 will have 12 subjects, who will stay in the clinical research center during 4 periods.
Group 2 will have 12 subjects, who will stay in the clinical research center during 3 periods.
The study is planned for Group 1 to participate in 4 treatment periods (including a food effect period), and Group 2 to participate in 3 treatment periods (with no food effect period).

Study burden and risks

Procedures: pain, light bleeding, haematoma and possibly an infection

Contacts

Public
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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Male
18-65 years of age
BMI 18.5 - 29.9 kg/m2 (inclusive) and body weight >50 kg

Exclusion criteria

Positive pre-study Hepatitis B, Hepatitis C, HIV
Diagnosed as not-healthy

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-04-2011
Enrollment:	24
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:	21-03-2011
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	EUCTR2010-024085-22-NL
CCMO	NL36000.056.11