DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED STUDY TO EVALUATE THE SAFETY, TOLERABILITY AND PHARMACOKINETICS OF SINGLE ASCENDING DOSES AND THE EFFECT OF FOOD ON ORAL WCK 4873 IN HEALTHY ADULT VOLUNTEERS

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To determine the safety and tolerability of single ascending doses of oral WCK 4873 in healthy subjects. To evaluate the pharmacokinetic (PK) profile of single ascending doses of oral WCK 4873 in healthy subjects.To evaluate the effects of food on...

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

Summary

ID

NL-OMON38693

Source
ToetsingOnline

Brief title
WCK 4873 Phase 1 SAD FE Study

Condition

- Respiratory tract infections

Synonym
Bacterial Pneumonia, Respiratory Tract Infections

Research involving
Human

Sponsors and support

Primary sponsor: Wockhardt Bio AG
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: Bacterial Pneumonia, Respiratory Tract Infections

Outcome measures

Primary outcome

PK

Safety

Tolerability

Secondary outcome

NA

Study description

Background summary

WCK 4873 is a new investigational compound that may eventually be used for the treatment of bacterial respiratory tract infections. A respiratory tract infection is an infection of the mucous membrane of the respiratory tract (nose, throat, airways and lungs). In the air you breathe, many pathogens such as viruses and bacteria are present. Once a virus or bacteria settles in the mucous membrane of the respiratory tract it will result in an infection. The most common symptoms of respiratory tract infections are: coughing, sore throat, hoarseness, runny nose, headache and fever.

Study objective

To determine the safety and tolerability of single ascending doses of oral WCK 4873 in healthy subjects.
To evaluate the pharmacokinetic (PK) profile of single ascending doses of oral

WCK 4873 in healthy subjects.
To evaluate the effects of food on the tolerability and PK profile at selected doses of WCK 4873 in healthy subjects.

Study design

A phase 1, randomized, double-blind, single center prospective, placebo-controlled, sequential cohort study in 78 healthy male and female subjects.

Cohorts 1 and 2 will receive a single dose of WCK 4873 or matching placebo under fasting conditions on Day 1.
Subjects in Cohorts 3 and 4 will receive a single oral dose of WCK 4873 in a 2 way crossover design, i.e., in one period under fasting conditions and in the other period under fed conditions.
Cohorts 5, 6 and the optional Cohort 7 will receive a single oral dose of WCK 4873 or matching placebo under fasting or fed condition.

Screening and follow-up:
During screening and follow-up clinical laboratory, full physical examination, ECG; at eligibility screening will be performed amongst others: medical history, urine tests and drug screen, HBsAg, anti-HBc, anti HCV, anti-HIV 1/2

Observation period:
Cohort 1, 2, 5, 6, 7 (Cohort 7 is optional): one period in clinic from -18 h up to 72 h after start of drug administration
Cohort 3, 4: two periods in clinic from -18 h up to 72 h after start of drug administration

Assesments during the study conduct:
On pre-defined timepoints blood will be collected for measuring the PK of WCK 4873 and PMN.
There will also be collected blood for measuring protein binding of WCK 4873 on pre-defined timepoints
Besides to blood, urine and feces will be collected to measure PK and the metabolites of WCK 4873

Safety will be assessed during the study by means of clinical laboratory, physical examination, ECGs and measuring LFTs on pre-defined timepoints.

Intervention

Single dose of WCK 4873 in the form of tablets up to a maximum of 1200 mg

Study burden and risks

Procedures: pain, light bleeding, heamatoma, possibly an infection.

Contacts

Public
Wockhardt Bio AG

Baarerstrasse 43
Zug 6300
CH
Scientific
Wockhardt Bio AG

Baarerstrasse 43
Zug 6300
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

healthy male or female
18 - 65 years inclusive
BMI 18.0 - 30.0 kg/m2 inclusive
non-smoker

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS.
Participation in another drug study within 60 days prior to randomization.
Any donation of blood(products) or significant blood loss within 60 days prior to drug administration

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-03-2013
Enrollment:	78
Type:	Actual

Ethics review

Approved WMO Date:	06-03-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-03-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	25-06-2013
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	EUCTR2013-000628-32-NL
CCMO	NL43633.056.13