A Phase 1 randomized, double-blind study to investigate the single and multiple dose safety, tolerability and pharmacokinetics of WCK 4282 (FEP-TAZ) upon intravenous administrations in healthy volunteers

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Part 1To evaluate the safety, tolerability, and pharmacokinetics (PK) of multiple intravenous doses of FEP-TAZ 4 g (2 g cefepime + 2 g tazobactam) and FEP-TAZ 3 g (2 g cefepime + 1 g tazobactam) administered every 8 hours (q8h) in healthy adult...

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

Summary

ID

NL-OMON43462

Source
ToetsingOnline

Brief title
W-4282-103 (CS0252)

Condition

- Bacterial infectious disorders

Synonym
Bacterial infections

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Pharmacokinetics, Safety, Tolerability

Outcome measures

Primary outcome

Safety, tolerability and pharmacokinetics.

Secondary outcome

N.A.

Study description

Background summary

The study drug is WCK 4282 (FEP-TAZ), Wockhardt*s proprietary injectable, antibacterial combination product consisting of cefepime (FEP) and tazobactam (TAZ).

Study objective

Part 1
To evaluate the safety, tolerability, and pharmacokinetics (PK) of multiple intravenous doses of FEP-TAZ 4 g (2 g cefepime + 2 g tazobactam) and FEP-TAZ 3 g (2 g cefepime + 1 g tazobactam) administered every 8 hours (q8h) in healthy adult volunteers for 10 days.

Part 2
To evaluate the safety, tolerability, and pharmacokinetics (PK) of single intravenous doses of FEP-TAZ 4 g (2 g cefepime + 2 g tazobactam), 2 g of cefepime and 2 g of tazobactam administered in healthy adult volunteers.

Study design

This study is a 2 part study in healthy adult subjects to be conducted in a single center.
Part 1 is a randomized, double-blind, placebo controlled, multiple intravenous dose study.
Part 2 is a double-blind, single intravenous dose, randomized, three period cross-over study with a washout of at least 96 hours (maximum 98 hours) between successive dosing occasions and after last dose.

Intervention

The study will start with a screening visit. During the screening visit standard medical assessments including safety laboratory tests (blood draw, urine collection), an alcohol breath test, urine drug screen, a physical examination, ECG and a vital signs measurement will be performed.

During study the subjects will enter the clinic, will receive medication as a q8h regimen for 10 days (part 1) or three single doses on three different days (part 2). They will be asked on a regular basis for possible side effects, blood will be drawn for safety and PK measurements, urine will be collected for safety and PK measurements and vital signs and ECG will bechecked regularly during the confinement period.

Finally a follow-up examination will be performed. During this visit the subjects will be asked for possible side effects, blood will be drawn for safety, the vital signs/ECG will be checked and a physical examination will be conducted.

Study burden and risks

Cefepime and Tazobactam have each been on the market for approximately 20 years. Both the compounds have been extensively evaluated in animal and human trials.

Cefepime: The most frequently reported side effects observed in multiple dose trials were: local reactions including inflammation of a vein, local reactions of pain and/or inflammation, rash, diarrhea, nausea, vomiting, itching, fever and headache.

Tazobactam: The most frequently reported side effects observed in multiple dose trials were: diarrhea, headache, constipation, nausea, insomnia, rash, vomiting, upset stomach, itching, stool changes, fever, restlessness, candidiasis, hypertension, dizziness, abdominal pain, chest pain, edema, anxiety, rhinitis and shortness of breath.

Recently, 12 volunteers participated in the first part of this clinical trial.
The following side effects have been reported by the 10 of the 12 volunteers:

infusion site reaction (tenderness and erythema at the infusion site, and redness of the skin), increased white blood cell counts, loose stool, abdominal pain and an increased body temperature. The reported side effects were mild to moderate in intensity. The infusion site reactions were most likely caused by the low quantity of diluent in which the study drug was dissolved. To prevent these infusion site reactions in this trial, the quantity of the diluent in the final formulation has been increased.

The blood collection procedure is not dangerous, but may cause discomfort or bruising. Occasionally, fainting, bleeding or an infection at the blood sampling site can occur.

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 or female, between 18 and 65 years of age both (inclusive)

Exclusion criteria

Clinical significant abnormalities at medical research.

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):	27-01-2016
Enrollment:	55
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	not applicable
Generic name:	Cefepime / Tazobactam

Ethics review

Approved WMO

Date:	13-01-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-01-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-03-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-03-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-03-2016
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	EUCTR2015-005587-42-NL
CCMO	NL56105.056.16