A First in Human, Phase 1, Randomized, Double-blind, Placebo-controlled, Single Ascending Total Daily Dose Study to Assess Safety, Tolerability, and Pharmacokinetics of Single and Multiple Intravenous Infusion of OMN6 in Healthy Subjects

Published: 27-01-2022
Last updated: 06-04-2024

Primary objective: To evaluate the safety and tolerability of single ascending i.v. doses of OMN6 in healthy young and elderly adult subjects.Secondary objective: To evaluate OMN6 PK in plasma following single ascending i.v. doses in healthy young...

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

Summary

ID

NL-OMON51720

Source
ToetsingOnline

Brief title
CS0379-200475 Omnix

Condition

- Bacterial infectious disorders

Synonym
treatment of infections

Research involving
Human

Sponsors and support

Primary sponsor: Omnix Medical
Source(s) of monetary or material Support: Omnix Medical

Intervention

Keyword: first in human, pharmacokinetics, safety, tolerability

Outcome measures

Primary outcome

• Safety and tolerability parameters include: physical examination, infusion

site reactions/local tolerability, AEs, clinical laboratory values, vital

signs, 12-lead ECG, and renal safety biomarkers.

Secondary outcome

• Plasma PK parameters for OMN6 include, but are not limited to: Cmax, Tmax,

t1/2, AUC0-last, AUC0-inf, CL, CLss, Vd and Vss.

Study description

Background summary

Antimicrobial resistance (AMR) is rapidly spreading worldwide, there is a great unmet need for new classes of antibiotics to treat drug resistant hospital associated infections. Multi-drug resistant (MDR) bacteria such as Acinetobacter baumannii (AB), especially Carbapenem-resistant AB (CRAB), are a major part of this healthcare challenge. AB is designated number one on the WHO/CDC pathogen-priority list. Infections are characterized by rapid development of resistance to multiple classes of antimicrobial drugs used as standard of care (SoC) including carbapenems. AB has the ability to acquire resistance through several mechanisms, which has led to the emergence of strains that are resistant to all commercially available antibiotics. Moreover, having evolved as a significant hospital pathogen, it has acquired the ability to resist desiccation and disinfectants. Since their discovery, antibiotics

have served as the cornerstone of modern medicine. AMR has led to the emergence of untreatable superbugs that are now threatening the basic practice of modern medicine. A new generation of effective antibiotic drugs is urgently needed. OMN6 was shown to be highly effective against MDR bacteria. The unique mechanism of action (MoA) employed by OMN6 demonstrates a complete lack of resistance or cross-resistance against its antimicrobial activity, allowing OMN6 to be positioned as a first-line treatment in case of severe and life-threatening infections. Efficiently eliminating resistant bacteria where the Standard of Care (SoC) drugs fail, without the fear of losing a new anti-infective agent due to resistance, OMN6 may provide an alternative to currently available antimicrobial therapies.

Study objective

Primary objective: To evaluate the safety and tolerability of single ascending i.v. doses of OMN6 in healthy young and elderly adult subjects.
Secondary objective: To evaluate OMN6 PK in plasma following single ascending i.v. doses in healthy young and elderly adult subjects.

Study design

In Cohorts 1 to 5, the study drug is planned to be administered as a single i.v. infusion of 3 hours to healthy young adults. In Cohorts 6 to 9, doses are planned to be administered as split i.v. infusions to healthy young adults; in Cohort 6 and 7, the dose will be administered as two 3-hour infusions with 8 hours between start of infusions and in Cohort 8 and 9, the dose will be administered as three 3-hour infusions with 8 hours between start of infusions. In Cohort 10, the study drug is planned to be administered as a single 3-hour i.v. infusion to healthy elderly subjects.

Intervention

OMN6 or matching placebo

Study burden and risks

Since the study is being executed in healthy volunteers, there are no anticipated benefits of the IMP. Please see the IB for further information.

Contacts

Public
Omnix Medical

High-Tech Village Givat Ram Campus N.A.
Jerusalem 91391
NL
Scientific
Omnix Medical

High-Tech Village Givat Ram Campus N.A.
Jerusalem 91391
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Provision of signed and dated, written informed consent prior to any study-specific procedures.
2. Healthy male and female subjects aged 18 to 59 years (young population), inclusive, or 60 years and older (elderly population) at the time of Screening.
3. A body mass index (BMI) between 18.0 to 28.0 kg/m2, inclusive at Screening.
4. Females must have a negative pregnancy test at Screening and on Day -1. Woman of childbearing potential must be willing to use a highly effective method of contraception with a failure rate of < 1% per year, be sexually inactive or have a sterilized partner during the study and for at least 3 months after the (last) study drug administration. If a hormonal contraceptive is used, it must have been initiated at least 1 month before the first study drug administration. Woman of non-childbearing potential will be confirmed at Screening by fulfilling one of the following criteria:
* Postmenopausal defined as amenorrhea for at least 12 months following cessation of all exogenous hormonal treatments and with follicle-stimulating hormone (FSH) levels >=30 mIU/mL.
OR

* Documentation of irreversible surgical sterilization by hysterectomy, bilateral oophorectomy or bilateral salpingectomy but not tubal ligation.
5. Male subjects should be willing to use acceptable methods of double barrier contraception i.e., condoms and spermicide, from Day 1 until at least 3 months after the (last) study drug administration.
6. Male subjects must not donate sperm from Day 1 until at least 3 months after the (last) study drug administration.

Exclusion criteria

1. History of any clinically important disease or disorder which, in the opinion of the Investigator, may either put the subject at risk because of participation in the study, or influence the results or the subject*s ability to participate in the study.
2. Subject has creatinine clearance (according to Cockcroft-Gault formula) <90 mL/min (young population) of <60 mL/min (elderly population).
3. Any clinically important illness, medical/surgical procedure or trauma within 4 weeks of the (first) administration of the study drug, as judged by the PI.
4. Any positive result at Screening for serum hepatitis B surface antigen, hepatitis C antibody, and human immunodeficiency virus (HIV).
5. Female subject is pregnant or lactating.
6. Abnormal vital signs, after 10 minutes (semi-)supine rest at Screening or on Day -1, defined as any of the following:
Systolic blood pressure >140 mmHg (young population) or >150 mmHg (elderly population).
Diastolic blood pressure >90 mmHg.
Heart rate <40 or >100 bpm.
Two (2) re-tests may be performed at Screening or Day -1.

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):	28-03-2022
Enrollment:	104
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Nap.
Generic name:	Nap.

Ethics review

Approved WMO Date:	27-01-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-02-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-03-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-03-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-06-2022

Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-07-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-08-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-09-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-11-2022
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	EUCTR2021-001865-18-NL
CCMO	NL80298.056.22