A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single and Multiple Ascending Dose Study of the Safety, Tolerability, Pharmacokinetics of Minocin® (minocycline) for Injection in Healthy Adult Subjects

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* The primary objective is to assess the safety and tolerability of single and multiple intravenous doses of Minocin IV when administered to healthy adult subjects.* The secondary objective is to assess the pharmacokinetics of single and multiple...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45336

Source
ToetsingOnline

Brief title
MDCO-MIN-16-02 (CS0275)

Condition

- Other condition

Synonym
Not applicable

Health condition

Acinetobacter infections

Research involving
Human

Sponsors and support

Primary sponsor: Medicines Company
Source(s) of monetary or material Support: Ministerie van OC&W,Medicines Company;Innovative Medicines Initiative.

Intervention

Keyword: A Phase 1, Pharmacokinetics, Safety, Tolerability

Outcome measures

Primary outcome

Safety, tolerability and pharmacokinetics.

Secondary outcome

Not applicable.

Study description

Background summary

Minocycline is a tetracycline derivative. The approved indication for Minocin IV in the United States includes the treatment of infections due to susceptible strains of several important Gram-positive and Gram-negative pathogens, including Acinetobacter species.

Study objective

* The primary objective is to assess the safety and tolerability of single and multiple intravenous doses of Minocin IV when administered to healthy adult subjects.
* The secondary objective is to assess the pharmacokinetics of single and multiple intravenous doses of Minocin IV when administered to healthy adult subjects.

Study design

This is a double-blind, randomized, placebo-controlled, single- and multiple ascending dose study of up to 6 doses/cohorts of Minocin IV.
Each cohort will consist of 10 subjects (8 active drug and 2 placebo).

Intervention

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

During the study the subjects will enter in the clinic, will receive medication at.....

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

Study burden and risks

The risk of having an (serious) adverse events following administration of Minocin IV is very small and of a nature that can be expected following administration of intravenous doses of tetracycline antibiotics, the type of drugs to which Minocin IV belongs.

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

1. A signed informed consent form, the ability to understand the study conduct and tasks that are
required for study participation, and a willingness to cooperate with all tasks, tests, and examinations as required by the protocol, whether in the research unit or after discharge, for the
duration of the study;
2. Male or female between 18 and 50 years of age inclusive;
3. Subject has a body mass index (BMI) *18 kg/m2 and * 30 kg/m2;
4. Subject is non-smoker or smokes up to 5 cigarettes per day (or equivalent).
5. Subject is in good health based on medical history and physical
examination findings and has no clinically meaningful safety laboratory abnormalities (Haematology, blood chemistry, and urinalysis) or 12-lead ECG results, as assessed by the Principal Investigator (PI);
6. Vital signs (BP, pulse, respiratory rate and temperature) measured at screening/baseline must
be within the following ranges: SBP *90 to *150 mm Hg, DBP *45 to *90 mm Hg; Heart Rate * 45 to *90 bpm (taken after resting in a supine position for at least 5 minutes);
7. Expectation that intravenous access will be sufficient to allow for ease of study drug infusion,
and for all protocol required blood sampling to take place;
8. Subject commits to remaining admitted in the research unit for the course of the study;
9. Female subject is surgically sterile, postmenopausal: period of amenorrhea
for at least 2 years, or if of childbearing potential, agrees to abstinence or to use at least 2 acceptable methods of birth control (e.g. prescription oral contraceptives, contraceptive injections, contraceptive patch, intrauterine device, barrier methods, etc.) or male partner sterilization alone, between the first dose (Day 1) and for 90 days after the completion of the study.

Exclusion criteria

1. Has any condition, including findings in the medical history or in pre-study assessments

that
constitutes a risk or a contraindication for the participation in the study or completing the study;
2. Positive breath test for alcohol and/or positive urine test for drugs of abuse at Screening and
Day -1 Visits;
3. Has a history or presence of alcohol/drug abuse within 2 years. Alcohol abuse is defined as regularly consuming >3 units/day (21 units per week for men), >2 units/day (14 units/week) for
women. A unit is defined as a can of 4% beer (330 mL), approximately 190 mL of 6-7% beer (malt liquor), a glass of 40% spirits (30 mL), a glass of wine (100 mL);
4. Subject shows positive hepatitis B surface antigen (HBsAg), hepatitis C virus antibodies (anti-
HCV), or human immunodeficiency virus (HIV) I/II antibodies and antigen tests;
5. Subject has active or ongoing candida infection;
6. Blood or plasma donation within past 2 months;
7. Females who are pregnant or nursing or who have a positive pregnancy test result at the screening Visit or Day -1 prior to dosing;
8. Males who are unwilling to practice abstinence or use an acceptable method of birth control
during the entire study period and for 90 days after the completion of the study (i.e. condom with
spermicide, where locally available) ;
9. Presence of known raised intracranial pressure;
10. Use of retinoids (e.g., Isotretinoin);
11. History of significant hypersensitivity or allergic reaction to any of the tetracycline class of
antibiotics or the components of those antibiotics;
12. Receipt of any investigational medication or investigational device during the last 30 days prior
to randomization;
13. Treatment with any prescription, vitamins or OTC drugs, within 2 weeks or five half-lives, whichever is longer, or herbal nutritional supplements within 2 weeks of screening, with the exception of acetaminophen/paracetamol for minor headache. Subjects will not be allowed to receive medications for the duration of the study (except the abovementioned acetaminophen/paracetamol). Birth control or other hormone replacement is also permitted as
long as it has been taken at a stable dose for at least three months before the Screening Visit and remains stable for the duration of the study;
14. A QTcF >480 msec;
15. Calculated creatinine clearance less than 50 mL/min (Cockcroft-Gault method) at screening or
check-in (Day -1)
16. Unable or unwilling, in the judgment of the Investigator, to comply with the protocol;
17. An employee of the Investigator, the study center, the sponsor or The Medicines Company with
direct involvement in the proposed study or other studies under the direction of that

Investigator
or study center, or a family member of the employee or the Investigator:
18. Prior enrollment in any minocycline study including prior cohorts in this trial;

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):	11-04-2017
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Minocycline for Injection
Generic name:	N.A.

Ethics review

Approved WMO

Date:	06-04-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	11-04-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-07-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-07-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-07-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-11-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-11-2017
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	EUCTR2016-002246-24-NL
CCMO	NL61330.056.17