Pharmacokinetics of clindamycin in overweight patients

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Primary Objective: To develop a pharmacokinetic model of clindamycin in patients of different BMI categories to determine the relevant obesity related covariates. Secondary Objective(s):To determine the variability and influence of clindamycin…

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

Summary

ID

NL-OMON45669

Source
ToetsingOnline

Brief title
CLIPO

Condition

- Bacterial infectious disorders

Synonym
not applicable

Research involving
Human

Sponsors and support

Primary sponsor: Gelre Ziekenhuizen
Source(s) of monetary or material Support: Gelre Ziekenhuizen

Intervention

Keyword: Clindamycin, Obesity, Overweight, Pharmacokinetics

Outcome measures

Primary outcome

Clearance and volume of distribution. These parameters will be estimated from the measured plasma concentrations by nonlinear mixed effect modelling. Plasma concentrations will be measured by a validated method using liquid chromatography * tandem mass spectrometry.

Secondary outcome

* Absorption rate constant and oral bioavailability.

* Body weight (kg), height (cm). These parameters will be used for BMI classification and to explore the optimal weight scaling factor (e.g. TBW, LBW, ABW, etc.).

* Multi-frequency bioelectrical impedance analysis (MBIA) will be used to determine body composition. Fractional masses (intracellular/extracellular water, fat) are explored as alternative weight scaling factors. The MBIA will not be used in case of an implanted cardioverter defibrillator (ICD) or when standardized measurement is not possible for practical reasons.

* Unbound clindamycin fraction, calculated from the total and free plasma concentration of clindamycin before and after separation of plasma proteins.

Study description

Background summary

Obesity is a worldwide problem for years. Besides the risk of an increased body mass index (BMI) on the development of cardiovascular diseases, diabetes and different types of cancer, it is well known that obesity is associated with inflammatory processes [2,3]. Because of the growing problem of obesity clinicians face the fact that there isn*t much information available to make the right dosing decisions in obese patients. Obesity is associated with pathophysiological changes that can influence pharmacokinetics of drugs in important matter. Clindamycin is a lincomycin antibiotic and is effective against anaerobe and Gram-positive aerobe bacteria. To date sufficient and specific pharmacokinetic data on clindamycin in obese patients are lacking. It is plausible that current dosing regimens lead to sub-therapeutic plasma concentrations and consequently inadequate treatment in the growing obese population

Study objective

Primary Objective: To develop a pharmacokinetic model of clindamycin in patients of different BMI categories to determine the relevant obesity related covariates.

Secondary Objective(s):
To determine the variability and influence of clindamycin plasma protein binding.
To compare the pharmacokinetic target achievement by using modelling and simulation.

Overall Aim: To develop rational dosing regimens for clindamycin in patients of different body weight classification.

Study design

This project is a prospective open multi-center observational cohort study.

Study burden and risks

The risks for participating in this study are considered to be minimal. There are no direct benefits of this study for the study patients. The results of the study will provide insight into the pharmacokinetics of clindamycin in overweight patients.

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. Age >18 years;
2. Treatment at regular dosing intervals with intravenous or oral clindamycin for at least 48 hours on day 0 (see Study procedures).;
3. Having signed the Informed Consent form.

Exclusion criteria

1. Administration of medication with a known pharmacokinetic interaction (e.g. rifampicin, HIV protease inhibitors).;
2. Inability to understand the nature of the trial and the procedures required.;
3. Self-reported pregnancy.;

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-01-2018
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	09-10-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20286
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2017-000588-34-NL

Register	ID
CCMO	NL61042.091.17
OMON	NL-OMON20286