Concentratie van clindamycine in bloed bij patiënten met overgewicht

Published: 14-02-2018
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0-hypothesis: no clinically relevant difference in clindamycin exposure (AUC/MIC) in overweight patients using 70 kg as a reference body weight

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20286

Source
NTR

Brief title
CLIPO

Health condition

infection clindamycin overweight obesity pharmacokinetics

Sponsors and support

Primary sponsor: Gelre Hospitals, Apeldoorn/Zutphen
Albert Schweitzerlaan 31
7334 DZ Apeldoorn
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Non-linear mixed effect pharmacokinetic model

Secondary outcome

- Variability of plasma protein binding
- Pharmacokinetic target achievement

Study description

Background summary

Rationale: To date sufficient and specific pharmacokinetic data on clindamycin in obese patients are lacking. Obesity is a widely recognized worldwide problem. 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 [3,4]. 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. It is plausible that current dosing regimens lead to sub-therapeutic plasma concentrations and consequently inadequate treatment in the growing obese population

Objective: Primary Objective: To determine the pharmacokinetics of clindamycin in patients of different weight categories who are treated for an infection caused by a clindamycin susceptible pathogen

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 population: Hospitalized patients (≥18 years old) with an infection treated with intravenous or oral clindamycin.

Main study parameters/endpoints: Clearance and distribution volume. Secondary parameters are absorption rate constant, bioavailability, weight, height, unbound clindamycin fraction and body composition. These parameters will be estimated from the measured plasma concentrations by non-compartimental analysis and nonlinear mixed effect modelling. Plasma concentrations will be measured by a validated method using liquid chromatography –

tandem mass spectrometry.

Study objective

0-hypothesis: no clinically relevant difference in clindamycin exposure (AUC/MIC) in overweight patients using 70 kg as a reference body weight

Study design

0, 0.5, 1, 1.5, 2, 4, 6 and 8 hours after administration

Intervention

n.a.

Contacts

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Eligibility criteria

Inclusion criteria

- Age > 18 years
- Treatment at regular dosing intervals with intravenous or oral clindamycin for at least 48 hours on day of blood sampling. Subject can be included twice if route of administration

changes.
- Having signed the Informed Consent form.

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-01-2018
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-02-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45669
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6877
NTR-old	NTR7055
CCMO	NL61042.091.17
OMON	NL-OMON45669

Study results