Concentratie van clindamycine in bloed bij patiënten met overgewicht

Gepubliceerd: 14-02-2018 Laatst bijgewerkt: 13-01-2025

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20286

Bron
Nationaal Trial Register

Verkorte titel
CLIPO

Aandoening

infection clindamycin overweight obesity pharmacokinetics

Ondersteuning

Primaire sponsor: Gelre Hospitals, Apeldoorn/Zutphen
Albert Schweitzerlaan 31
7334 DZ Apeldoorn
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Non-linear mixed effect pharmacokinetic model

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

n.a.

Contactpersonen

Publiek

Albert Schweitzerlaan 31
H.J.M. van Kan
Gelre Hospitals, Apeldoorn/Zutphen, Dept. of Clinical Pharmacy

Apeldoorn 7334 DZ
The Netherlands
+31555818639 (secr.)

Wetenschappelijk

Albert Schweitzerlaan 31
H.J.M. van Kan
Gelre Hospitals, Apeldoorn/Zutphen, Dept. of Clinical Pharmacy

Apeldoorn 7334 DZ
The Netherlands
+31555818639 (secr.)

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	29-01-2018
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-02-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45669
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten