Ciprofloxacin pharmacokinetics after IV and oral administration in cachectic elderly patients

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Primary Objective: - To study the pharmacokinetics (CL, Vd, and F) of ciprofloxacin in cachectic elderly patients and compare with normal weight participants.Secondary Objective(s): - To assess the influence of covariates (such as TBW, LBW, serum...

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

Summary

ID

NL-OMON50150

Source
ToetsingOnline

Brief title
CIPCEP

Condition

- Bacterial infectious disorders

Synonym
cystitis, Pneumonia, Urinary tract infection

Research involving
Human

Sponsors and support

Primary sponsor: Tergooiziekenhuizen
Source(s) of monetary or material Support: Tergooi wetenschapsfonds

Intervention

Keyword: cachexia, ciprofloxacin, elderly, pharmacokinetics

Outcome measures

Primary outcome

A farmacokinetic model using Non Linear Mixed Effects Modelling (NONMEM). Model

validation using bootstrap

method or Sampling Importance Resampling (SIR). The final modelwill be used for

Monte Carlo simulation for multipledosing

regimens and higher dosages.

Secondary outcome

NA

Study description

Background summary

Life expectancy is increasing and elderly patients are prone to malnutrition and underweight, partly as a result of high age itself or as a result of comorbidities. Dosingguidelines are based on studies in which elderly and patients with divergent weight are often excluded. Pharmacokinetic studies are needed to design adequate dosing regimens for special patient populations like cachectic elderly as cachexia and age are known to be associated with physiological changes which may influence pharmacokinetics.
There is increasing evidence that frail elderly are subject to adverse health effects as a result of pneumonia or urinary tract infections. Ciprofloxacin is an important therapeutic resource for both indications. In addition, outcomes are known to be improved after timely administration of a right dose of the right drug. However, for cachectic elderly patients the right ciprofloxacine dose is currently unknown.

Ciprofloxacin is available as oral or intravenous preparation. However, the bioavailability in cachectic elderly is unknown.
Therefore it seems prudent to conduct a trial in a cohort of cachectic elderly patients who are treated with ciprofloxacin in routine clinical care (400mg IV

or 500mg PO).
These subjects will be compared to the pharmacokinetics in a normal-weight group that was already recruited in the AMIGO trial (2015-004814-84).
This study aims to provide clinical information that will be used to determine an optimal dosing strategy for obese patients through modeling and simulation.

Study objective

Primary Objective:
- To study the pharmacokinetics (CL, Vd, and F) of ciprofloxacin in cachectic elderly patients and compare with normal weight participants.
Secondary Objective(s):
- To assess the influence of covariates (such as TBW, LBW, serum creatinine, Groningen frailty index, MUST score, metabolomics and Glomerular filtration rate (GFR)) on the pharmacokinetics of ciprofloxacin.
- To develop dosing recommendations for ciprofloxacin in cachectic elderly patients.

Study design

This is a prospective observational study which will be performed in cachectic elderly patients being treated with PO ciprofloxacin (n=15) or IV ciprofloxacin (n=10) in routine clinical care. A control group of 8 healthy volunteers that was recruited for the AMIGO study will be used(EudraCT: 2015-004814-84).

Study burden and risks

The risk-classification is assessed as negligible to the patient population receiving ciprofloxacin. Patients will receive ciprofloxacin under routine clinical care. The main burden associated with the study concists of a single venapuncture if no venous catheter is available. The samples will be obtained from this catheter, therefore sample collection itself not of additional burden.

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

- Treated witch ciprofloxacin as a part of routine clinical care
- >75 years of age
- At least one of the following:
o BMI <19
o Unintended weight loss of >10% of total body weight in the previous 12 months
o weight <60kg and BMI<21
o BMI <21 and a positive MUST score for malnutrition
- Participant is able and willing to sign the Informed consent before screening evaluations.

Exclusion criteria

- Subjects may not be critically ill, i.e. not be admitted to the ICU

Study design

Design

Study phase: 4

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-11-2020
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	18-06-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL72345.100.20