Defining the optimal dose for continuous flucloxacillin infusion using pharmacokinetic modelling ;The FLUCON-study

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Step 1 Primary objective: To describe the population pharmacokinetics of flucloxacillin for non-critically ill patients and determine the influence of covariates (demographics and renal function) on the kinetics of flucloxacillin. Step 2Primary...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON43049

Source
ToetsingOnline

Brief title
Flucon

Condition

- Bacterial infectious disorders

Synonym
infectional disease

Research involving
Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Flucloxacillin kinetics

Outcome measures

Primary outcome

Main study parameters/endpoints: Part A: (step 1) A quantitative description of the pharmacokinetics flucloxacillin in non-critically ill patients: changes in (unbound) flucloxacillin level-time profiles and the possible relationship with renal function and demographics. Step 2: A dosing regime for continuous administration of flucloxacillin in which 90% of the population exceeds 100% ft>MIC (with a maximum unbound flucloxacillin concentration of 7,5mg/L). Part B: The percentage of patients exceeding the PK target of 100% ft>MIC (with a maximum unbound flucloxacillin concentration of 7,5mg/L) with the new dosing regime.

Secondary outcome

Part B: A description of the tolerability of the new continuous dosing scheme.

Study description

Background summary

The small spectrum antibiotic flucloxacillin is approved in an intermittent dosing regime. The antibacterial activity of flucloxacillin is time dependent so continuous infusion is probably more effective. Furthermore, for some patients continuous dosing can have practical benefits. As it stands, the optimal flucloxacillin dosage for continuous infusion is unknown. Studies indicate that a lower dosage of continuous infusion might be sufficient.

Study objective

Step 1
Primary objective: To describe the population pharmacokinetics of flucloxacillin for non-critically ill patients and determine the influence of covariates (demographics and renal function) on the kinetics of flucloxacillin.

Step 2
Primary objective: To determine the continuous dosing scheme of flucloxacillin to obtain a pharmacokinetic target of 100% fT>MIC (with a maximum unbound flucloxacillin concentration of 7,5mg/L) for 90% of the population.

Step 3
Primary objective: To validate the new continuous dosing scheme of flucloxacillin on the pharmacokinetic endpoint of 100% fT>MIC (with a maximum unbound flucloxacillin concentration of 7,5mg/L) for 90% of the population.

Study design

Part A: multi centre, cross-sectional non-randomized observational study in 30 patients. On two separate days flucloxacillin levels are measured.
Part B: multi centre, non-randomized interventional study. Patients will receive the new continuous dosing scheme and therapeutic drug monitoring (TDM) will be conducted.

Intervention

Part B: Patients will receive the new dosing scheme for continuous flucloxacillin therapy and TDM will be conducted.

Study burden and risks

Flucloxacillin is a registered product and used within the indication and not in combination with other products.
The remaining risks for the subjects participating in the study are acceptable since part A involves mainly standard care. Only additional blood samples are taken, which has a low risk for complications. In general the risk for participation in this study is regarded low. The risk of suboptimal dosing in part B is minimized by performing therapeutic drug monitoring as soon as possible. Suboptimal dosages will be detected soon and dose adjustments can be made.
Benefits for patients participating in part A will be that they will receive information on the optimal dosage of flucloxacillin, when administrated as a continuous infusion. Participants in part B might experience less side effects.

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

Part A;In order to be eligible to participate in this study, a subject must meet;all of the following criteria:;- The patient is at least 18 years of age;- The patient has started with intravenous flucloxacillin as indicated by;their physician;At least 10 of the 30 patients are treated with flucloxacillin for a bacteriemia;Part B;In order to be eligible to participate in this study, a subject must meet;all of the following criteria:;- The patient is at least 18 years of age;- The patient has an indication for the treatment of flucloxacillin with;continuous infusion as indicated by their physician

Exclusion criteria

Part A and B;A potential subject who meets any of the following criteria will be;excluded from

participation in this study because of the altered;pharmacokinetics:;- The patient who is admitted to the intensive care unit;- Pregnant women

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-01-2017
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ffloxapen
Generic name:	Flucloxacillin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	27-06-2016
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	27-07-2016
Application type:	Amendment

Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	23-08-2016
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	01-12-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	29-05-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	EUCTR2016-000930-24-NL
CCMO	NL57100.075.16