Defining the optimal dose for continuous flucloxacillin infusion

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28330

Source
NTR

Brief title
Flucon study

Health condition

infections
kinetics
infusion
flucloxacillin

Sponsors and support

Primary sponsor: Deventer Hospital
Source(s) of monetary or material Support: Deventer Hospital, investigator initiated

Intervention

Outcome measures

Primary outcome

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. Part B: The percentage of patients exceeding the PK target of 100% fT>MIC with the new dosing regime.

Secondary outcome

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

Study description

Background summary

waiting for MEC approval

Study objective

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 design

after finishing flucloxacillin therapy

Intervention

Part A: none

Part B: altered dosage flucloxacillin

Contacts

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Eligibility criteria

Inclusion criteria

- The patient is at least 18 years of age

- The patient has started with intravenous flucloxacillin as indicated by their physician

Part B

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

The patient who is admitted to the intensive care unit

- Pregnant women

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2016
Enrollment:	30
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL5578
NTR-old	NTR5934
Other	METC Zwolle/Isala : 16.06103 dz

Study results

Summary results

none