ISRCTN52722850 https://doi.org/10.1186/ISRCTN52722850

To study ciprofloxacin pharmacokinetics in patients who are critically ill and undergoing continuous dialysis

Submission date	Recruitment status
14/04/2011	No longer recruiting
Registration date	**Overall study status**
19/05/2011	Completed
Last Edited	**Condition category**
31/01/2012	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2004-002195-42

Protocol serial number
300704 CT Number: CT900/425/1

Study information

Scientific Title
An evaluation of ciprofloxacin pharmacokinetics in critically ill patients undergoing continuous veno-venous haemodiafiltration

Study objectives
Under dosing of antibiotics has enabled the genesis of resistant strains and this is particularly an issue with fluoroquinolones. Altered drug pharmacokinetics, due to disease, results in variable antimicrobial drug clearance in critically ill patients (antibiotic regimens are often developed on the basis of drug disposition in non-critically ill volunteers) and further complicates the selection of appropriate dosing schedules for these patients. The goal of ciprofloxacin therapy is to maximise the 24 hour Area Under the Curve/Minimum Inhibitory Concentration and the peak /MIC ratios. A number of papers have highlighted the requirement for a re-evaluation of currently recommended antimicrobial dosage regimens for critically ill patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
St James's Hospital and the Adelaide and Meath Hospital, Dublin, Incorporating the National Children's Hospital Joint Ethics Committee Reference Number 041008/7804

Primary study design
Observational

Study design
Open, prospective, observational pharmacokinetic study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Patients on dialysis

Interventions
1. Timed serum samples were collected during each dosage interval and ultrafiltrate during 7 dosage intervals (1 per patient)
2. Effluent fluid was collected for the entire dosage interval
3. The volume of each hourly batch was recorded and a 40ml sample was taken for analysis
4. Aliquots from each sample were analysed for ciprofloxacin concentration and for creatinine determination
5. Total ciprofloxacin concentrations in serum and effluent were measured by a HPLC method
6. Serum concentrations, from an indwelling arterial cannula, were measured immediately before the infusion was started, immediately after the infusion finished and at 2,3,4,6,8 and 12 hours post infusion where the dosage interval was 12 hours
7. When the prescribed dosage interval was 24hr samples were also taken at 18 and 24hrs
8. Exact sampling times were recorded

Intervention Type
Other

Phase

Not Applicable

Primary outcome(s)
To obtain reliable estimates of ciprofloxacin pharmacokinetic parameters for patients in intensive care unit (ICU) on Continuous veno-venous hemodiafiltration (CVVHDF)

Key secondary outcome(s)
To describe achieved pharmacodynamic parameters in these patients

Completion date
31/10/2006

Eligibility

Key inclusion criteria
1. Aged over 18
2. Requiring Continuous Veno Venous Hemodiafiltration (CVVHDF)
3. Requiring ciprofloxacin therapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Aged less than 18
2. Patient / relative consent denied

Date of first enrolment
01/01/2005

Date of final enrolment
31/10/2006

Locations

Countries of recruitment
Ireland

Study participating centre
Department of Intensive Care Medicine
Dublin
Ireland
24

Sponsor information

Organisation
Trinity College Dublin (Ireland)

ROR
https://ror.org/02tyrky19

Funder(s)

Funder type
University/education

Funder Name
Trinity College Dublin (Ireland)

Alternative Name(s)
Coláiste Thríonóid Naofa Neamhroinnte na Banríona Eilís gar do Bhaile Átha Cliath, Trinity College, the University of Dublin, Trinity College Dublin, The University of Dublin, Coláiste na Tríonóide, Baile Átha Cliath, TCD

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/08/2011		Yes	No