

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

Submission date 14/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/05/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/01/2012	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Study design

Open, prospective, observational pharmacokinetic study

Primary study design

Observational

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 na Tríonóide, Baile Átha Cliath, TCD

Funding Body Type
Private sector 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