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

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

Submission date
14/04/2011

Recruitment status
No longer recruiting

Registration date
19/05/2011

Overall study status
Completed

Last Edited
31/01/2012

Condition category
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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24

Additional identifiers

EudraCT/CTIS number
2004-002195-42

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
To describe achieved pharmacodynamic parameters in these patients

Overall study start date
01/01/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

7 = 3 female, 4 male

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
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Sponsor information

Organisation
Trinity College Dublin (Ireland)

Sponsor details
c/o Prof Owen Corrigan
School of Pharmacy and Pharmaceutical Sciences
Trinity College Dublin
Dublin
Ireland
2

Sponsor type
University/education

Website
http://www.tcd.ie/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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