

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

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Maria Donnelly

Contact details

Department of Intensive Care Medicine

The Adelaide and Meath Hospital

Dublin Incorporating the National Children's Hospital (AMNCH)

Tallaght

Dublin

Ireland

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Additional identifiers

EudraCT/CTIS number

2004-002195-42

IRAS number**ClinicalTrials.gov number****Secondary identifying numbers**

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

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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