Cefizox clinical assessment protocol / Wellcome Foundation Ltd.

CEFIZOX*
CLINICAL ASSESSMENT PROTOCOL

*Trade Mark

Aim

To determine the clinical efficacy of Cefizox in the treatment of licensed indications.

Introduction

Ceftizoxime (Cefizox) is an amino-thiazolyloximino cephalosporin with a high degree of ß-lactamase stability, which is combined with a broad antibacterial spectrum, including both gram-positive and gram-negative organisms. It is licensed to treat such indications as genito-urinary infections including gonorrhoea, lower respiratory tract infections, intra-abdominal infections, septicaemia, and skin and soft tissue infections in adults and children down to the age of three months.

Literature to date

Ceftizoxime has been the subject of extensive *in vitro* and *in vivo* research. A bibliography is included.

Study population

The investigator will choose suitable cases from in-patients under his or her care.

Inclusions

1. Licensed indication.
2. Patient aged over three months.
3. Likely to have, or known to have, an infection sensitive to ceftizoxime.

Exclusions

1. Known hypersensitivity to penicillins or cephalosporins.
2. Subsequent demonstration of organisms resistant to ceftizoxime.
3. Pregnancy.
4. Significant co-incident disease which would make evaluation difficult.

Consent

Each patient, or his or her parents or guardian, will give informed consent.

Approval

Local Ethical Committee approval will be obtained. The study conforms to the terms of the Declaration of Helsinki, 1964.

Method

Those patients who fulfil the inclusion and exclusion criteria will be selected. Both patients in whom ceftizoxime is used as the initial therapy, and patients in whom it is instituted following failure of a first-line therapy, can be included.

Dosage

This will be according to data sheet recommendations, and can be by the intravenous or intramuscular route. When 2g is administered intramuscularly, the dosage should be divided and given in different large muscle masses.

General guidelines

Adults	Dosage	Route
Urinary Tract Infections	0.5-1g 12-hourly	IM or IV
Gonorrhoea	1g as single dose	IM
Other infections	1-2g 8-12-hourly	IM or IV
Severe or life-threatening infections	2-3g 8-hourly	IM or IV

Children over the age of three months

30-60mg/kg bodyweight/day in 2-4 divided doses, increased in severe or life-threatening infections to 100-150mg/kg bodyweight/day. The total dose should not exceed the adult dose.

Dosage in renal impairment

Modification of dosage is necessary in patients with impaired renal function. For an adult, an initial loading dose of 0.5-1g is given IM or IV and a maintenance dosing schedule as shown below is followed (no data are available for children):

Creatinine clearance ml/min	Less severe infections	Severe or life-threatening infections
79-50	500mg 8-hourly	0.75-1.5g 8-hourly
49-5	250-500mg 12-hourly	0.5-1g 12-hourly
4.0 (dialysis)	500mg 48-hourly or 250mg 24-hourly	0.5-1g 48-hourly or 0.5g 24-hourly

Dialysis

Patients undergoing haemodialysis do not require supplemental dosing following the procedure, but the administration of the drug should be timed so that the patient receives the dose at the end of dialysis.

Data handling

All data will be made available to The Wellcome Foundation Ltd for evaluation and appropriate statistical analysis, after entering on the assessment proformas.

Criteria for withdrawal

1 Wish of patient.

2 Significant adverse reaction.

3 Isolation of resistant causative organism.

4 Inadequate clinical response.

Adverse reactions

Any serious or significant adverse reaction should be reported as soon as possible to the Scientific Services Division of The Wellcome Foundation Ltd, Crewe Hall, Crewe, Cheshire CW1 1UB Tel: 0270 583151

Supply of drug

The Wellcome Foundation Ltd will supply ceftizoxime for use in this study.

Scientific Services Division
The Wellcome Foundation Ltd, Crewe, Cheshire

Wellcome