

Material and Methods The dye ingress test with methylene blue was used as CCIT for both CSTDs with ten samples of meropenem drug vials of three brands (n = 60). A media fill test was performed with both CSTDs (n = 300 per CSTD, 150 carried out in a safety cabinet and 150 under non-classified environmental conditions).

Results In all samples of both CSTDs methylene blue was absent after visual inspection and spectrophotometric analysis. The nutrient media of one sample with CSTD A, reconstituted in a safety cabinet, was contaminated whereas none of the CSTD B samples with reconstitution in a GMP grade A environment were contaminated. Under non-classified environmental conditions, one sample of CSTD A and two samples of CSTD B were contaminated.

Conclusion and Relevance In conclusion, both CSTDs connected to meropenem vials of three brands are in compliance with the closure integrity by using the dye ingress. The aseptic procedure of CSTB B was validated with the media fill test when reconstituted in a GMP grade A environment, but failed for CSTD A. The added value of CSTDs in a hospital (pharmacy) remains debatable without a clearly demonstrated closure integrity when bedside reconstitution is done. Hospital pharmacists are strongly advised to perform sufficient and adequate closure integrity tests with CSTDs before implementing them in clinical use.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-008 SLOW ANAKINRA DESENSITISATION PROTOCOL DESIGN FOR DELAYED HYPERSENSIBILITY REACTION

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Background and Importance Anakinra, a recombinant human IL-1 receptor antagonist, is indicated in rheumatoid arthritis (RA) with a good safety profile, nonetheless its administration has been associated with a severe delayed injection-site reaction without a fully understood pathogenesis. To deal with that several desensitisation schemes have been published in the literature.

Aim and Objectives The aim is to describe the design of a slow desensitisation protocol (SDP) for subcutaneous (SC) anakinra for patients who have failed the rapid desensitisation scheme (RDP).

Material and Methods We introduce a 72 year-old patient diagnosed for RA and treated with SC anakinra after failing other treatment lines who presents severe injection-site reactions after 3 weeks of treatment. An attempt was made to desensitise quickly but it was not tolerated either. As there were no more lines of treatment available, it was decided, in collaboration with allergists, to design a SDP.

It was designed for 56 doses of increasing concentrations (until 100 mg dose). Lower dose was 0,1 mg and dose change was performed every 3-4 days. Solutions were elaborated in the Pharmacy Service. Starting from a mother solution (MS) of 100 mg anakinra in physiologic serum 0,9% (SF) to a final volume of 1mL (1:1 solution) two anakinra dilutions were

made: 1:10, 1:5. The MS was prepared from anakinra 100 mg/0,67 ml injection. The dilution 1:10 was made by taking 0,5 ml from the MS and SF until 10 ml (concentration 5 mg/ml). The dilution 1:5 was prepared by diluting 1 ml from 1:10 dilution until 5ml final volume with SF (concentration 1 mg/ml).

To prevent hypersensitivity reactions it was needed to add antihistamines during the SDP.

Results Although RDP was not well tolerated, the proposed scheme had satisfactory results. At first the lowest dose (0,1 mg) was not tolerated by the patient, so it was decided to add antihistamines during the process. If any dose could react, the dose change was done instead of 3 after 5-7 days. Actually, the patient has completed the doses until 50 mg without adverse reactions.

Conclusion and Relevance The SDP proposed by allergist in collaboration with hospital pharmacist has allowed the safe administration of anakinra, avoiding a loss of the last therapeutic line possible in a patient with RA.

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3PC-009 CYCLOPHOSPHAMIDE SURFACE CONTAMINATION IN A ROBOTIC CHEMOTHERAPY COMPOUNDING PROCESS

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Background and Importance There is a wild consensus about the risks associated to the occupational exposure to hazardous drugs, but recent studies have shown that there is still surface contamination in pharmacies preparing antineoplastic drugs. The main reason for the implementation of robotic compounding systems is to improve safety; for the patient and for healthcare workers, avoiding repetitive strain injuries and hazardous drugs exposure.

Aim and Objectives The aim of this study was to evaluate cyclophosphamide exposure of pharmacy nurses during the robotic chemotherapy compounding process.

Material and Methods The sampling areas were selected after being identified as the highest risk of personal contamination in a risk assessment. Wipe samples were taken from vials, infusion bags, gloves, and different locations of the robotic system. Surface monitoring was performed using a semi-quantitative device based on thin layer immunochromatography. The sampling was performed at the end of the workday over several days before cleaning process to identify the highest potential degree of contamination to which healthcare workers could be exposed.

Results Cyclophosphamide compounding was performed during the study days and several months before. There was no cyclophosphamide spill in the three months prior to the study. External contamination was measured on 15 vials and 10 bags of cyclophosphamide and on 10 gloves and 5 robot areas after cyclophosphamide compounding during 5 non-consecutive days. There were not Cyclophosphamide contamination over the detection limit of 0.5ng/cm² in none of the samples