3PC-025 STABILITY STUDY OF STANDARDISED FLUID THERAPY PREPARED BY THE PHARMACY DEPARTMENT TO TREAT PAEDIATRIC DIABETIC KETOACIDOSIS

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Background and Importance The Pharmacy Department prepares and distributes fluid therapy (2 bags-system) for the treatment of diabetic ketoacidosis (DKA) in the paediatric emergency unit.

The implementation of this procedure has improved patient safety, since standardised preparations are used only the rhythm being modified according to the patient's needs.

The two bags system consists in sets of two bags of maintenance electrolytes in 1 litre of 10% dextrose or isotonic saline. Unfortunately, their expiration date was only 7 days due to the lack of data on stability.

In order to improve the convenience and reduce wastage, we designed and carried out a physical-chemical stability study of these solutions.

Aim and Objectives The objective of this study was to evaluate the physical and chemical stability of these solutions prepared in the Pharmacy Department to manage paediatric DKA.

Material and Methods

1. The two bags system contains:
   - Solution 1: Potassium (k) 38meq/l, phosphate (P) 59 mg/dl, magnesium (Mg) 5mg/dl and Sodium (Na)143meq/l in isotonic saline.
   - Solution 2: The same electrolytes concentration in dextrose 10%.
2. We prepared 8 units of each solution, half of them were stored at room temperature (23ªC), and half of them in the refrigerator (4°C).
3. We analysed the electrolytes concentration and made visual inspection for physical changes on the following days: 0 (d0), 14 (d14), 28 (d28), 49 (d49) and 92 (d92).

The chemical analysis was performed by the Laboratory Department through the following techniques: sodium and potassium by indirect potentiometry with selective electrode, phosphate by phosphomolybdate reaction; magnesium and glucose by enzymatic technique.

The physical analysis was determined in pharmacy through visual inspection searching for changes in colour and matter particles against a white and a black background.

The results were expressed in mean+/-SD. It was accepted a deviation <5%.

Results The electrolytes concentration remained stable during the study period. The visual inspection showed physical stability. Table 1 summarises the results.

Conclusion and Relevance The results show the stability of solutions in the period of study. Nevertheless, the beyond-use-date will be re-evaluated when a validated sterility test is performed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-026 COST SAVINGS ASSOCIATED WITH ROMIPLOSTIM REPACKAGING IN A PATIENT WITH IDIOPATHIC THROMBOCYTOPENIC PURPURA

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Background and Importance

Background Romiplostim is indicated for the treatment of primary immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (corticosteroids, immunoglobulins). This drug has an important economic impact, in this sense it has been decided to start a protocol for the use of romiplostim which has been established to group patients or dispense two repackaged romiplostim pre-filled syringes for each patient fractionating vials according to the patient´s dose in syringes as a saving strategy.

Aim and Objectives

Objective Evaluating and quantifying the cost saving of the optimisation of the use of romiplostim vials through repackaging into syringe under aseptic conditions.

Material and Methods Retrospective study from January to June 2023 and patients diagnosed from ITP and treated with romiplostim were included. A protocol is being implemented, which consists of dispensing two repackaged romiplostim prefilled syringes (7 days expiration according to Good Practice Guide of preparation of medications in hospital Pharmacy Service) for each patient or grouping the patients receiving treatment with romiplostim and fractionating the vial in syringes to adjust to the recommended dose according to the Summary of Product Characteristics in a flow laminar cabinet. Variables collected: demographics (sex/age), number of patients, and economic (price of romiplostim vial). Data were collected from pharmacy electronic dispensing records.

Abstract 3PC-025 Table 1

Solution 1		(Mean ± SD)										Diff (%)
		T0		T14		T28		T42		T92		
	Theoric range	23ºC	4ºC	23ºC	4ºC	23ºC	4ºC	23ºC	4ºC	23ºC	4ºC	
Sodium(meq/l)	136.1-150.4	144,2 ± 2,7	143,8 ± 2,6	137,3 ± 2,7	137,0 ± 2,6	142,3 ± 2,7	142,0 ± 2,6	143,8± 2,7	143 ± 2,6	141,5± 2,7	141,5± 2,6	NS
Potassium(meq/l)	36,2- 40,0	37,3 ± 1,4	41,4 ± 2,9	37,8 ± 1,4	37,7 ± 2,9	37,3 ± 1,4	38,3 ± 2,9	38,6 ± 1,4	38,6 ± 2,9	38,3 ± 1,4	38,3 ± 2,9	NS
Phosphate (mg/dl)	56.06-62	56,3 ± 2,1	62,4 ± 4,9	57,3 ± 2,1	58,5 ± 4,9	57,5 ± 4,9	56,5 ± 4,9	58,5 ± 2,1	58,5 ± 2,1	55,6 ± 2,1	55,6 ± 2,1	NS
Magnesium (mg/dl	5,4-5,9	5,9 ± 0,4	7,5 ± 1,4	5,2 ± 0,4	5,3 ± 1,4	5,1 ± 0,4	5,0 ± 1,4	5,8 ± 0,4	5,7 ± 1,4	5,6 ± 0,4	5,5 ± 1,4	NS
Solution 2		**(Mean ± SD)**										
		T0		T14		T28		T42		T92		
	Theoric range	23ºC	4ºC	23ºC	4ºC	23ºC	4ºC	23ºC	4ºC	23ºC	4ºC	
Sodium(meq/l)	136.1-150,4	149,25 ± 4,6	149 ± 3,5	141,5 ± 4,6	140,3 ± 3,5	146 ± 4,6	144,5 ± 3,5	146,75 ± 4,6	145 ± 3,5	145,7 ± 4,6	144,3 ± 3,5	NS
Potassium(meq/l)	36,2- 40,0	40,8 ± 1,4	42,3 ± 2,2	38,6 ± 1,4	37,9 ± 2,2	38,8 ± 1,4	37,9 ± 2,2	39,2 ± 1,4	38,5 ± 2,2	39,1 ± 1,4	38,4 ± 2,2	NS
Phosphate (mg/dl)	56.06-62	59,9 ± 3,2	65,8 ± 4,7	58,7 ± 3,2	58,6 ± 4,7	57,5 ± 3,2	57,2 ± 4,7	59,7 ± 3,2	58,9 ± 4,7	56,6 ± 3,2	56,1 ± 4,7	NS
Magnesium (mg/dl	5,4-5,9	5,8 ± 0,3	6,13 ± 0,4	5,4 ± 0,3	5,6 ± 0,4	5,2 ± 0,3	5,2 ± 0,4	5,8 ± 0,3	5,6 ± 0,4	5,7 ± 0,3	5,6 ± 0,4	NS
Dextrose			10,8± 1,5%	-	10,9± 1,5%	9,6± 3,4%	11,0± 1,5%	9,4 ± 3,4%	10,0± 1,5%	9,4 ± 3,4%	9,5± 1,5%	NS

Results A total of 16 patients suffering from ITP are being treated in our hospital with romiplostim, 50% of them are men, and median age 54 years old (21–90). This treatment has cost a total of € 240,561.95 for these 6 months (January to June), however, if patients had been dispensed two repackaged romiplostim pre-filled syringes or had been grouped and given appointment on the same of the week and romiplostim repackaging had been performed under aseptic conditions, the total cost had been € 158191,48 therefore the cost saving there would been € 82.370,47 (€ 164.740,94/year).

Conclusion and Relevance The dispensing of two romiplostim pre-filled syringes or the grouping of patients and the fractionation of romiplostim vials would suppose a saving of € 164.740,94 (saving of 86.342,21 mcg romiplostim, 345 vials of 250 mcg) every year. The repackaging could represent a significant economic saving in the treatment of idiopathic thrombocytopenic purpura, while contributing to maintaining the sustainability of the national health system.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No-conflict-of-interest

Conflict of Interest No conflict of interest.

3PC-027 USE OF AUTOMATED COMPOUNDING DEVICES IN PAEDIATRIC PARENTERAL NUTRITION: A GOOD WAY TO ENSURE SAFETY

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Background and Importance Parenteral nutrition (PN), particularly in paediatric patients, is a complex and high-risk therapy due to small volumes and high susceptibility. Expert recommendations advocate the use of automated compounding devices (ACD) to enhance the safety and quality of paediatric parenteral nutrition (PPN).

Aim and Objectives To evaluate the implementation of an ACD, taking into account criteria related to complexity of the task, safety and workload, as well as the quality and safety of the PN.

Material and Methods Observational and retrospective study from January to June 2023 in a tertiary care hospital. The number, volume, weight and composition of the PPNs prepared during this period were evaluated. Quality and safety of the admixtures were evaluated through the alerts observed (weight deviation). The weight limit deviation accepted was set in +/-5% for PPN over 100 mL and +/-3% for PPN with a volume of 100 mL or less. The impact on the workload will be assessed based on production times.

Results During the study period, 2.483 units were prepared, consisting of individualised PPN for 190 patients and stock preparations.

The breakdown below offers detailed information about the PNs, patient characteristics and the time needed for the whole compounding process, in paediatrics with the ACD and adults, where a vacuum filling machine is used:

An average of 27 nutrients were used to prepare the PPNs (minimum: 4, maximum: 33). In 2.133 units (86%) heparin was manually added after the completion of the compounding.

The range of weight deviation was [4,14%,-2,43%]. The median was 0,85%. No deviation >5% has been recorded in PPNs with a volume >100 mL. In PPNs with a volume <100 mL all deviations observed were <3%.

Conclusion and Relevance The use of an ACD has ensured process quality and safety, as no significant weight deviations were observed despite the diversity of volumes. Furthermore, it reduces the operator's handling, simplifying the task, minimising the risk of microbiological contamination and the likelihood of errors, without increasing the processing times compared to less precise methods.

Given the complexity of preparations and the achieved results, automating PPN preparation processes proves to be an

Volume of PN (mL)	Number of PN
< 50	50
50-100	274
100-250	730
250-500	354
> 500	1075
Total (units)	2483

Weight of the patient (kg)	Total
< 10	443
10-20	236
20-30	112
30-40	86
> 40	134
Total	1011

	Adult PN	Vacuum filling machine set up	Preparation of components	Total time
Mean time (min:sec)	4:03	9:07	43:55	57:05

	Pediatric PN	ACD set up	Preparation of components	Total time
Mean time (min:sec)	3:47	33:54	22:40	60:21