



INTRADIALYTIC CALCIPHYLAXIS IN RENAL PATIENTS. DEVELOPMENT OF AN INJECTABLE SOLUTION OF 25% SODIUM THIOSULFATE FOR TREATMENT. (TCH-022)

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BACKGROUND

Calciphylaxis (calcific uremic arteriopathy) is the ischemic ulceration of the skin caused by the metastatic calcification of the subcutaneous tissue and small arteries as a consequence of hyperparathyroidism in uremic patients.

OBJECTIVE

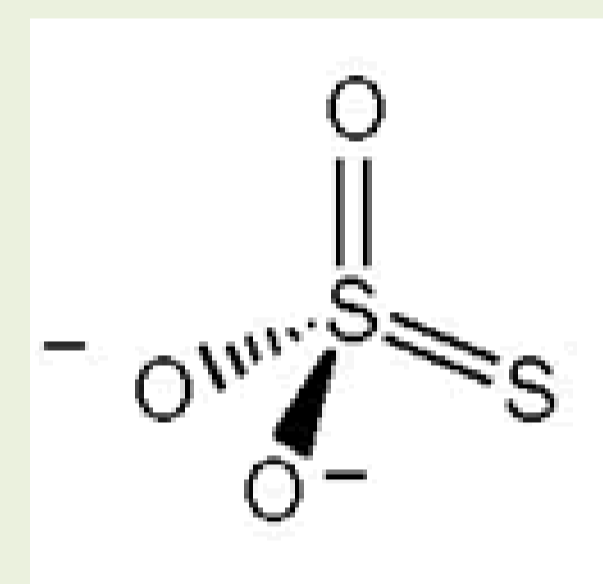
To describe the method of preparation and control of an injectable solution of 25% sodium thiosulfate for the treatment of intradialytic calciphylaxis in renal patients.

MATERIAL AND METHODS

Sodium thiosulphate is an **antioxidant, vasodilator and calcium chelator**.

The manufacturing process of the solution of 25% sodium thiosulfate is:

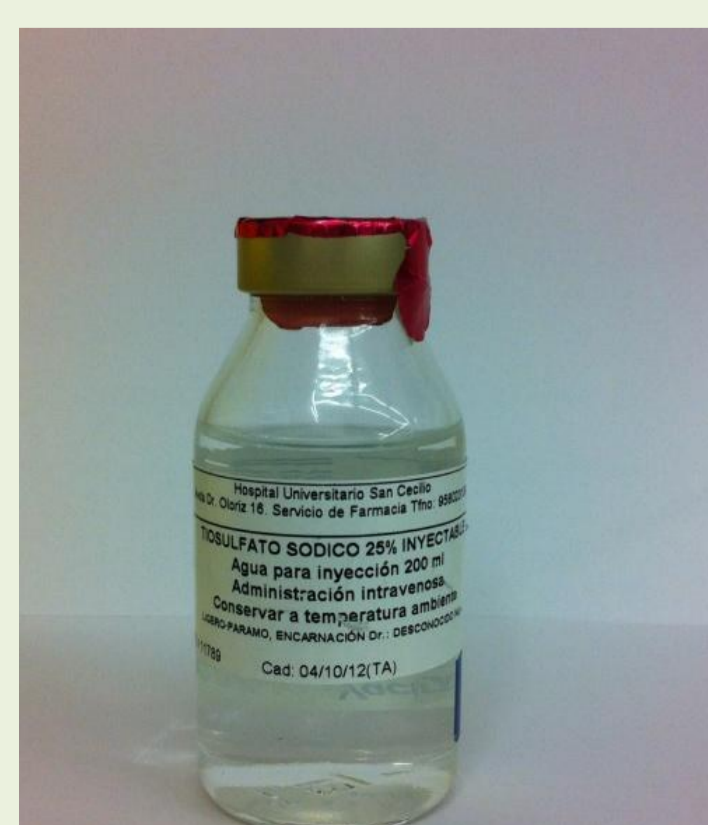
- **Ingredients:** Sodium thiosulfate pentahydrate: 25 g, water for injection (WFI): qs 100 ml.
- **Preparation:** To weigh the amount of sodium thiosulfate in a sterile beaker. Then, working in horizontal laminar flow hood, boiling API to eliminate CO₂. To dissolve the Thiosulfate in about 80 ml of boiled water. To check if the pH of the solution is between 6 and 9.5, otherwise adjusted with HCl or NaOH. Flush to 100 ml volumetric flask and make up a double filtration with 0.22 micron filter. Finally to pack with 50 ml syringe in sterile glass bottle and to label.



RESULTS

The result is a solution of 100 ml of 25% sodium thiosulfate, transparent, sterile and stable for 30 days in refrigerator. Likewise performing a visual particulate control of sterility by means of sowing in aerobic and anaerobic culture and a bubble point test to verify the integrity of the filters.

CONCLUSIONS



Proper preparation and control of the solution of 25% sodium thiosulfate has guaranteed its parenteral administration safely. The treatment was effective and well tolerated, making good progress in patients and improving their quality of life.