

Double-Blind Randomized Study: Efficacy and Safety of RENALOF in the Treatment of Patient Carriers of Renal Calcium Oxalate Lithiasis (2009)

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Introduction

The most common kidney stone is calcium, predominantly composed of calcium oxalate stones which is responsible for 1 in 1,000 hospitalizations per year and the recurrence rate is high, standing at 10 to 20% in the first two years and by 40-60% after ten years of the first episode.

Renalof (capsules of 325 mg) is a nutritional supplement that provides global actions on renal oxalate and calcium phosphate in the urinary tract, causing destruction and / or decrease.

We conducted a clinical trial to evaluate the efficacy and safety of Renalof in the treatment of recurrent calcium urolithiasis.

Renalof Ingredients

Agropyron Repens Extract (12 mg), Mannitol (88 mg), Corn Starch (200 mg), Magnesium Silicate (25 mg)

Methods

Phase III clinical trial placebo-controlled, randomized, two double-blind parallel group. The patients were recruited and treated at the Nephrology Institute of Cuba.

Inclusion criteria

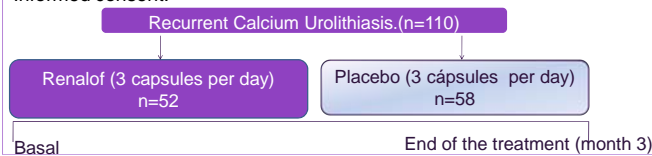
- Both sexes.
- Age between 18-65 years old.
- Presence of calcium oxalate urolithiasis.
- Patients with stones less than one centimeter.
- Informed consent.

Exclusion criteria

- Patients with stones larger than one centimeter.
- Pregnant woman.
- Oncoproliferative disease.
- Previous treatment for the destruction of the kidney stone.

End points

- Stone size.
- Stone numbers.
- Number of renal colic.
- Physical-Chemical disorders.
- Metabolic disorders.
- Days of hospitalization.
- Days with medical certification.
- Presence of adverse reaction.



Results

Figure 1: Evolution of the Stones' size

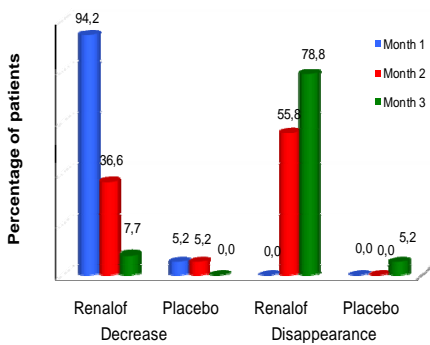


Figure 2: Number of kidney stones

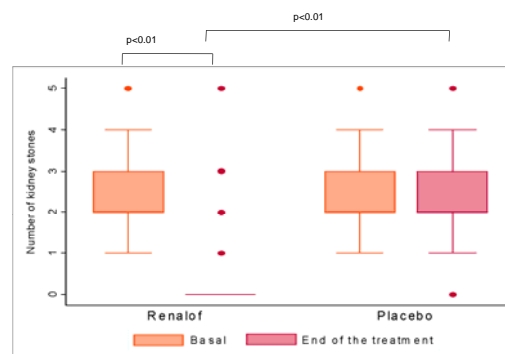
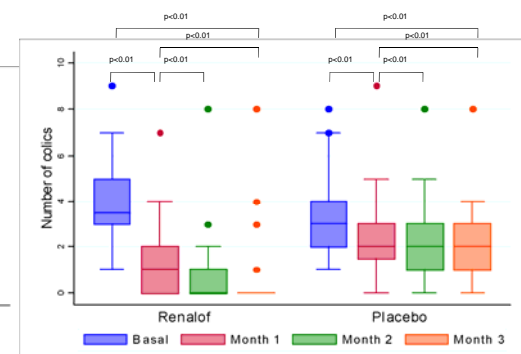


Figure 3: Number of renal colic



P<0.01 in all comparisons except in the disappearance of calculi (month 1), non calculated.

Figure 4: Hypercalciuria

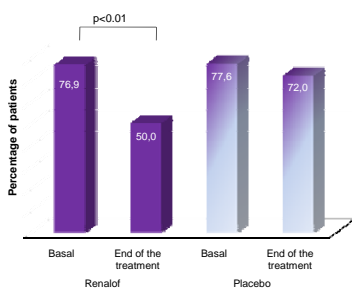


Figure 5: Ph*

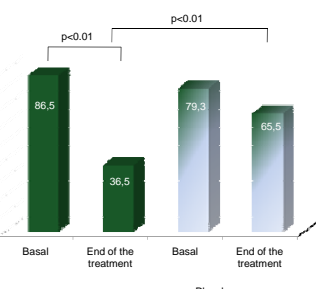


Figure 6: Phosphate activity group*

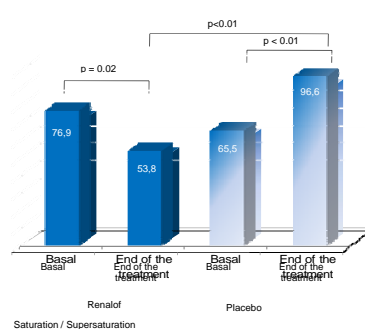
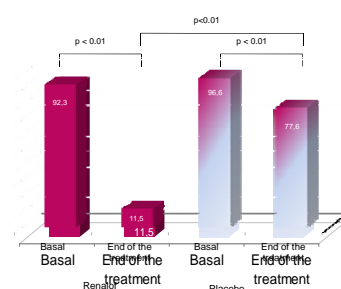


Figure 7: Urinary volume*



*: Acid / Alkaline

Saturation / Supersaturation

*: Low

Figure 8: Medical certificates

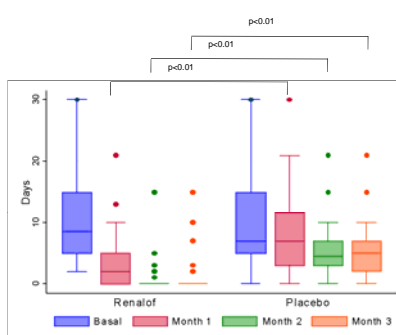
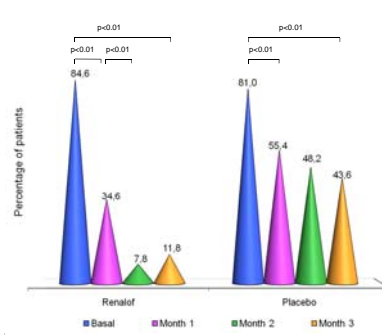


Figure 9: Hospitalised patients



- The hiperoxaluria, hypocitraturia and hyperuricosuria not differ before / after and between groups at the endpoint (p> 0.05).
- The oxalate activity product produces differences before / after only in the Renalof group.(p<0.01).
- The crystallization risk index shows differences before / after in the Renalof group (p <0.01) and between groups at the end of the treatment p <0.01).
- During the treatment there were no unexpected serious adverse events.

Conclusions

Renalof is effective and safe for the treatment of recurrent calcium urolithiasis.