

*Book of abstracts. LXXIX National Congress of Urology. Costa Adeje (Tenerife) 2014*

*Abstract no: P-118*

**Title: Utipro<sup>®</sup>: a new effective treatment for symptoms of acute cystitis**

Authors: García-Larrosa, Alejandro (1); Alexe, Octavian (2)

Institution: (1) Hospital of Viladecans (Barcelona). (2). University of Galati (Romania)

## **INTRODUCTION**

Utipro<sup>®</sup> is a new class III medical device approved for the control and prevention of urinary tract infections. It comes in capsules of gelatin stabilized complex containing hibiscus sabdariffa extract and propolis.

Objectives: To assess the effectiveness of Utipro<sup>®</sup> in controlling symptoms suggestive of acute cystitis, need for antibiotic rescue and adverse effects.

## **MATERIAL AND METHODS**

Multicenter, prospective, randomized (treatment and placebo), double-blind clinical trial. 60 patients (30 per arm).

Inclusion criteria: age  $\geq 18$ , one or more symptoms of cystitis (dysuria, urgency, suprapubic pain and / or organoleptic changes of urine), evolution  $\leq 72$  hours, positive urine dipstick (nitrite and / or leukocyte esterase).

Exclusion criteria: temperature  $\geq 37.5$  ° C, back pain, antibiotic treatment within 48 hours before, anatomical-functional abnormalities of the urinary tract, immunodeficiency, pregnancy, lactation.

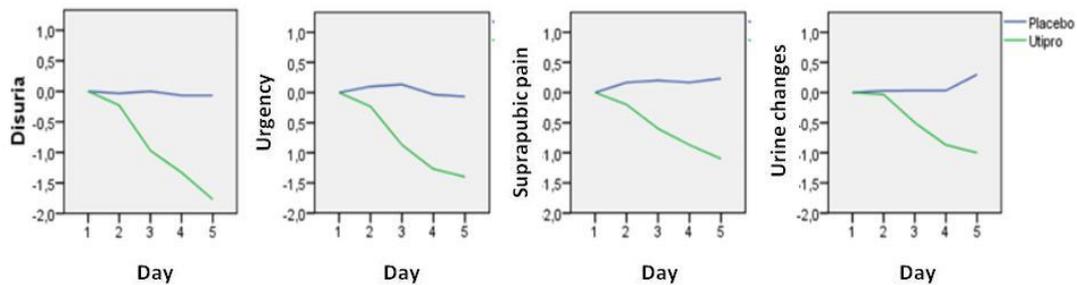
Variables analyzed: dysuria, urgency, suprapubic pain and organoleptic changes (quantitative scale of 0-3). Adverse effects (guides MEDDEV 2.7).

Intervention: 1 capsule Utipro<sup>®</sup> or placebo every 12 hours for 5 days. Follow up for 11 days. Poor response to treatment was considered with total symptom score  $\geq 1$ , indicating antibiotic.

## RESULTS

Symptomatic progression: mean difference in symptom scores between the last and the first day of treatment.

| Variable        | Utipro | Placebo | Differences between Utipro and Placebo | P (t Student) |
|-----------------|--------|---------|--|---------------|
| Dysuria         | -1,77  | -0,07   | -1,70 (CI 95% -2,22 to -1,18)          | < 0,001       |
| Urgency         | -1,40  | -0,07   | -1,33 (CI 95% -1,89 to -0,78)          | < 0,001       |
| Suprapubic pain | -1,10  | 0,23    | -1,33 (CI 95% -1,85 to -0,82)          | <0,01         |
| Urine changes   | -1,00  | 0,30    | -1,30 (CI 95% -1,85 to -0,75)          | <0,001        |
| Total score     | -5,27  | 0,40    | -5,67 (CI 95% -7,43 to -3,91)          | <0,001        |



Need for antibiotic: Utipro<sup>®</sup> 10%, 33.3% placebo ( $p = 0.028$ ). Relative risk for Utipro<sup>®</sup> 0.3 (confidence interval 95% 0.09 to 0.98).

Adverse effects: Utipro<sup>®</sup> 6.67%, 3.33% placebo ( $p = 0.5$ ). Utipro<sup>®</sup>, 2 patients (abdominal pain, diarrhea). Placebo, 1 patient (diarrhea). All mild

| Goals               | Utipro | Placebo | p     |
|---------------------|--------|---------|-------|
| Need for antibiotic | 10%    | 33,3%   | 0,029 |
| Adverse effects     | 6,67%  | 3,33%   | 0,5   |

## CONCLUSIONS

Utipro<sup>®</sup> improved symptoms associated with acute cystitis after 5 days of treatment compared to placebo, reducing the need for antibiotic treatment.