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**Dr. Robindera Kour**  
In Charge Consultant Surgery,  
Govt. Hospital Sarwal, Jammu,  
Jammu and Kashmir, India

**Dr. Gurpreet Kour**  
Medical Officer, Acharya Shri  
Chander College of Medical  
Sciences, Jammu, Jammu and  
Kashmir, India

**Dr. Iqbal Singh**  
Assistant Professor, Public Health  
Dentistry, Indira Gandhi  
Government Dental College,  
Jammu, Jammu and Kashmir,  
India

**Dr. KK Gupta**  
Consultant Surgeon, Govt.  
Hospital Sarwal, Jammu, Jammu  
and Kashmir, India

**Dr. Rajiv Sharma**  
Medical Superintendent, Govt.  
Hospital Sarwal, Jammu, Jammu  
and Kashmir, India

## Efficacy of fosfomycin trometamol and cefuroxime axetil in the treatment of UTI during pregnancy: A comparative study

**Dr. Robindera Kour, Dr. Gurpreet Kour, Dr. Iqbal Singh, Dr. KK Gupta  
and Dr. Rajiv Sharma**

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### Abstract

**Objective:** To compare the efficacy of fosfomycin trometamol and cefuroxime axetil in the treatment of urinary tract infections during pregnancy.

**Methods:** Prospective clinical study was conducted among pregnant women who were followed as part of routine prenatal care at Government Hospital Sarwal, Jammu, India with complaints of lower UTI were assessed. 60 patients were enrolled, divided into 2 equal groups for treatment with single-dose fosfomycin trometamol and 5-day courses of cefuroxime axetil. Follow-up was carried out after 5 weeks.

**Results:** The treatment groups did not differ significantly in terms of demographics, clinical compliance rate and adverse effects. But the patients who were taking 5-day courses of cefuroxime axetil showed statistically significant higher cure rate as well as lower recurrence rate as compared to fosfomycin trometamol group.

**Conclusion:** Treatment with a single dose of fosfomycin trometamol and 5-day courses of cefuroxime axetil were found similar in terms of compliance rate and adverse effects but effectiveness in curing the UTI significantly higher among patients who were taking 5-day courses of cefuroxime axetil therapy.

**Keywords:** Fosfomycin trometamol, cefuroxime Axetil, UTI

### Introduction

Urinary tract infections (UTIs) are one of the most well-known contaminations saw in pregnancy. The urinary tract experiences anatomical and physiological changes in pregnancy that can result in side effects and conditions influencing both the mother and the baby. Be that as it may, the visualization of UTIs is regularly acceptable if there is immediate assessment and quick treatment <sup>[1]</sup>. The point of treatment is to kill pathogenic microorganisms, re-foundation the sterility of urine, and stay away from the improvement of difficulties <sup>[2]</sup>. The more noteworthy trouble experienced in the analysis and treatment of intermittent UTI can build the quantity of facility visits required during pregnancy, which may be baffling, particularly for patients <sup>[3]</sup>.

Urinary tract infections are most commonly caused by Escherichia coli and over recent years an increasing number of strains produce  $\beta$ -Lactamase so that up to 50% of hospital isolates are resistant to amoxicillin and ampicillin. Similarly, the high usage of sulphonamids/trimethoprim combinations or trimethoprim alone has resulted in smaller increases in resistance. The stability of cefuroxime/ $\beta$ -lactamases particularly TEM, suggests that the ester will be a suitable alternative in therapy. There are many regimens for the treatment of urinary tract infections but in general, there has been emphasis on short courses of therapy and reduced dosage.

Cefuroxime has been extensively used with marked clinical success in the treatment of bacterial infections in hospitalized patients. It has a wide spectrum of bacterial activity against both Gram-positive and Gram-negative species and is resistant to the action of many  $\beta$ -lactamases. Cefuroxime is poorly absorbed, less than 1% from the gastrointestinal tract and therefore has only been available in parenteral form <sup>[4]</sup>. A new ester, cefuroxime axetil, has recently been developed for oral therapy. Hence the present study was conducted with the The aim of the present study was to compare the efficacy of single dose FT, a 5-day course of cefuroxime axetil (CA) in the treatment of uncomplicated lower UTIs during pregnancy.

### Correspondence

**Dr. Robindera Kour**  
In Charge Consultant Surgery,  
Govt. Hospital Sarwal, Jammu,  
Jammu and Kashmir, India

## Material and Methods

### Study design

A Prospective clinical study was conducted among pregnant women who were followed as part of routine prenatal care at Government Hospital Sarwal, Jammu, India with complaints of lower UTI were assessed.

### Ethical approval and Informed consent

The study protocol was reviewed by the Ethical Committee of the Hospital and granted ethical clearance. After explaining the purpose and details of the study, a written informed consent was obtained.

### Inclusion criteria

- Patients willing to participate in study.
- Pregnancy of at least 12 weeks of gestation
- Uncomplicated lower UTI

### Exclusion criteria

- Patients who are not willing to give written informed consent
- Those lost to follow-up
- Any chronic illnesses including diabetes mellitus

### Sample selection

The sample size was calculated using a prior type of power analysis by G\* Power Software Version 3.0.1.0 (Franz Faul, Universitat Kiel, Germany). The minimum sample size of each group was calculated, following these input conditions: power of 0.80 and  $P \leq 0.05$  and sample size arrived were 60 patients i.e 30 per group.

### Group-A

Patients underwent treatment with a single 3-gram dose of FT.

### Group-B

Patients underwent treatment with a 5-day, twice daily course of 500 mg/day of CA.

### Methodology

Urine analysis and culture were performed at baseline and at week 2 of treatment. Patients were requested to give midstream urine samples in sterile containers after cleaning the urethral entrance. Samples were centrifuged at 2000 rpm for 5 minutes (ARIS IQ500; DPC, Los Angeles, CA, USA), and sediments were examined microscopically to determine the percentage of leukocytes and bacteria.

Samples were inoculated on bloody agar and eosin-methylene blue agar for 30 minutes. Samples with 10<sup>5</sup> cfu/mL or more growth at 18–24 hours of incubation were examined microscopically. Samples with no growth at this time point were re-incubated for another 24 hours.

### Follow-up

Patients were followed-up after 2 weeks to assess the success of bacterial eradication, clinical efficacy in terms of persistence of complaints, and any adverse effects. Patients who had negative results for the urine culture at week 5 were considered to be successfully treated.

### Statistical analysis

The recorded data was compiled and entered in a spreadsheet computer program (Microsoft Excel 2010) and then exported to data editor page of SPSS version 19 (SPSS Inc., Chicago,

Illinois, USA). Descriptive statistics included computation of means and percentages. Student –test was used for the statistical analysis of the independent samples.

## Results

**Table 1:** Mean Duration (days) of symptoms among study population

Groups	Mean	Standard Deviation	p-value
Group A	6.29	1.59	0.910 (NS)
Group B	6.01	1.19	

Test applied: student t-test

**Table 2:** Mean Recovery time (Days) among study population

Groups	Mean	Standard Deviation	p-value
Group A	4.29	1.34	0.041 (Sig.)
Group B	2.98	1.23	

Test applied: student t-test

**Table 3:** distribution of adverse effects

Adverse Effects	Group A N=30	Group B N=30
Diarrhea	8 (26.7)	7 (23.3)
Nausea	5 (16.7)	3 (10.0)
Vomiting	4 (13.3)	3 (10.0)
Abdominal Pain	2 (6.7)	2 (6.7)
Vaginal discomfort	2 (6.7)	1 (3.3)

## Discussion

UTI is defined as a clinical picture including frequent urination, pain in the bladder area, and dysuria, as well as a bacterial count of 100 000 per mL or higher in midstream urine culture. However, a diagnosis of UTI might be established with lower amounts of bacteriuria<sup>[5, 6]</sup>. The objectives of UTI treatment are to eradicate microorganisms, obtain sterile urine, and prevent the development of complications<sup>[2]</sup>.

Pyelonephritis develops in about 20%–40% of pregnant women with complaints of lower UTI; therefore, clinicians should aim to reduce the risk of developing complications and recurrence by timely elimination of the uncomplicated lower UTI.

In the present study, the rate of compliance was significantly higher in the FT group than in the CA groups; this result might be attributed to the single-dose usage of FT. In addition, its adverse-effects profile was little higher in frequency than group CA. Similarly Warren *et al.*<sup>[7]</sup> reported rates of adverse effects of 26% in patients taking FT. In the study of Naber<sup>[8]</sup>, adverse effects were reported among 10.8%. Most adverse effects associated with FT are gastrointestinal complaints including diarrhea, nausea, and vomiting<sup>[9]</sup>.

In the present study higher cure was observed in the group B (CA) as compared to group A (FT) in another study conducted by Bayrak *et al.*<sup>[10]</sup> in which they investigated the efficacy of single-dose fosfomycin therapy among 84 pregnant women in their second trimester with asymptomatic bacteriuria. They did not find any significant differences between the two drugs in terms of cure rate. However, further studies should be performed to investigate whether shorter courses of CA and AC therapies would be equally effective. In addition, further studies should be performed on greater patient populations to enable grouping according to specific pathogens to determine pathogen specific antibiotic resistance.

It is often difficult to identify women with recurrent UTI at initial presentation because urine culture reports are not immediately available. This might lead to an increased number of clinic visits, which can be frustrating especially for patients.

In practice, treatment often has to be initiated before microbiologic results are obtained. Region-specific observational studies aimed at determining the specific types of UTI pathogens and their resistance patterns might help clinician to choose the right empiric treatment, thereby reducing the number of clinic visits required and increasing treatment efficacy.

### Conclusion

The present study concluded that the treatment with a single dose of fosfomycin trometamol and 5-day courses of cefuroxime axetil were found similar in terms of compliance rate and adverse effects but effectiveness in terms of curing the UTI significantly higher as well as less recurrence rate among patients who were taking 5-day courses of cefuroxime axetil as compared to single dose fosfomycin trometamol therapy.

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