International Journal of Life Sciences, Biotechnology and Pharma Research Vol. 14, No. 2, February 2025 Online ISSN: 2250-3137
Print ISSN: 2977-0122

DOI: 10.69605/ijlbpr_14.2.2025.190

**ORIGINAL RESEARCH**

# Role Of Prophylactic Antibiotics In Preventing Recurrent Urinary Tract Infections During Pregnancy: A Randomized Controlled Trial

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Received: 21 January, 2025 Accepted:16 February, 2025

**ABSTRACT**

**Background:** Recurrent urinary tract infections (UTIs) pose widespread risks at some stage in pregnancy, such as pyelonephritis, preterm hard work, and occasional beginning weight. Prophylactic antibiotic regimens had been proposed to lessen the occurrence of recurrent UTIs among pregnant girls at excessive risk; but, proof helping their efficacy and safety remains varied [1,2].

**Methods:** A randomized controlled trial was performed in one center in pregnant women with a history of recurrent UTIs. The patients were divided into two groups: Group A was given continuous low-dose prophylactic antibiotics, (nitrofurantoin 50 mg/day), and Group B was given no prophylaxis but were followed up intensively. The main outcome was the rate of recurrent UTI during pregnancy. Secondary endpoints were gestational age at birth, birth weight, and undesirable maternal or neonatal outcomes. Baseline and monthly until birth urinalyses, urine cultures, and maternal-fetal evaluation were conducted. Statistical tests comprised chi-square for categorical variables and t-tests for continuous outcomes.

**Results:** 200 pregnant women with a history of recurrent UTIs were recruited. The rate of recurrent UTIs was significantly lower in the prophylaxis group (15%) than in the control group (32%) ($p<0.05$). The frequency of asymptomatic bacteriuria during follow-up visits was also statistically lower in the prophylaxis group. There was no difference between the two groups in adverse maternal or neonatal outcomes. Low-dose nitrofurantoin was tolerated well, and compliance was high throughout the study.

**Conclusion:** Low-dose prophylactic antibiotic treatment in pregnant women with a past historyof recurrent UTIs has been found to have a great decrease in the incidence of recurrence without an enhancement of adverse outcomes for the mother or neonate. These data endorse the therapeutic use of prophylactic antibiotics in high-risk pregnancies, as a means to enhance maternal and fetal well-being.

**Keywords:** Prophylactic antibiotics; Recurrent urinary tract infection; Pregnancy; Nitrofurantoin; Randomized controlled trial



## INTRODUCTION

Urinary tract infection (UTI) is the most frequent bacterial infection seen in pregnancy and occurs in about 2–10% of pregnant women [1]. The pregnant woman's physiological changes, i.e., dilatation of the ureters, enlargement of the bladder, and hormonal status, make pregnant women susceptible to asymptomatic bacteriuria and symptomatic UTIs [2]. If left behind or not managed properly,

UTIs may recur to pyelonephritis, whose complications are maternal morbidity, preterm labor, and low birth weight [3]. Additionally, recurrent UTI is a specific concern, since recurrences can cause cumulative damage to tissue, antibiotic resistance, and greater medical expense [4].

Prophylactic antibiotic therapy has been hailed as prevention against recurrent UTIs in high-risk patients, including pregnant women with a history of multiple previous UTIs [5]. Among prophylactic modalities, low-dose nitrofurantoin has emerged as specific focus of interest for efficacy within the urinary tract, great safety during pregnancy (most notably during the second trimester), and fairly

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minimal effect on the overall microbiome relative to other broad-spectrum agents [6].Yet, reservations exist regarding the development of antibiotic resistance, masking symptomatic attacks, and the currently uncertain risk-benefit balance in heterogeneous populations [7].

Current literature on continuous and post-coital antibiotic prophylaxis in non-pregnant women indicates a significant decrease in recurrent UTIs [8]. However, there is limited high-quality randomized controlled data specifically addressing prophylactic antibiotic use for recurrent UTIs in pregnancy. In addition, guidelines for prophylactic antibiotic use in pregnancy are still heterogeneous, indicating continued controversy regarding safety and best administration schedules [3,7].

This randomized controlled trial (RCT) sought to determine if continuous low-dose prophylactic antibiotics would be effective in preventing recurrent UTIs in pregnant women without causing added maternal or neonatal risk. In particular, we suspected that pregnant women with a history of recurrent UTIs who were given a daily prophylactic antibiotic regimen during pregnancy would have a reduced rate of recurrent infection and similar pregnancy outcomes compared to those without prophylaxis. The findings of this research will offer evidence-based information to guide clinical practice guidelines for the treatment of recurrent UTIs in pregnancy, which could reduce risks for both mothers and fetuses [1–8].

Urinary tract infections (UTIs) are one of the most frequent bacterial infections that occur during pregnancy, with about 2–10% of pregnant women being affected [1]. The physiological alterations of pregnancy, such as ureteral dilation, increased bladder capacity, and hormonal changes, predispose pregnant women to both asymptomatic bacteriuria and symptomatic UTIs [2]. UTIs, if left untreated or poorly controlled, can develop into pyelonephritis, which carries with it an increased risk of maternal morbidity, preterm labor, and low birth weight [3]. In addition, the recurrent UTI poses a unique challenge since continuous infections can develop into cumulative damage to tissue, antibiotic resistance, and additional economic burden [4].

Prophylactic antibiotic protocols have been also suggested as one of the potential methods for averting recurrent UTIs in susceptible individuals, including pregnant women who have had numerous previous UTIs [5]. Among the prophylactic agents, low-dose nitrofurantoin has been particularly noted for its action in the urinary tract, good safety profile in pregnancy (especially in the second trimester), and relatively minimal effect on the wider microbiome relative to other broad-spectrum antibiotics [6]. Nonetheless, issues do exist regarding the potential risk of developing antibiotic resistance, possible masking of symptomatic episodes, and as yet undefined risk-benefit ratio in diverse populations [7].

Existing literature on continuous and post-coital antibiotic prophylaxis in non-pregnant populations suggests a marked reduction in recurrent UTIs [8]. Nonetheless, there is a paucity of high-quality randomized controlled trials specifically examining prophylactic antibiotic use for recurrent UTIs during pregnancy. Moreover, guidelines concerning prophylactic antibiotic use in pregnancy remain heterogeneous, reflecting ongoing debate about safety and optimal administration schedules [3,7].

This randomized controlled trial (RCT) was to test if continuous low-dose prophylactic antibiotics can prevent recurrent UTIs in pregnant women effectively without posing additional maternal or neonatal risks. More precisely, we hypothesized that pregnant women with history of recurrent UTIs who are put on a once-a-day prophylactic antibiotic regimen during pregnancy would have fewer cases of recurrent infections and similar pregnancy outcomes than those without prophylaxis. The findings of this research will yield evidence-based information to guide clinical practice guidelines on the treatment of recurrent UTIs in pregnancy, potentially reducing risks for mothers and fetuses [1–8].

## MATERIALS AND METHODS

**Study Design and Setting:** This randomized controlled trial was held inside the branch of Obstetrics and Gynecology of a tertiary care centre from January 2023 via December 2024. Institutional evaluation Board ethics approval was performed,and written knowledgeable consent become obtained from each challenge earlier than being enrolled.

**Participants and Eligibility Criteria:** Pregnant women 18–40 years old with singleton gestations at <20 weeks' gestation and a known history of having had at least two previous UTIs within the past 12 months were candidates for inclusion. Allergy or intolerance to nitrofurantoin, chronic kidney disease, sickle cell disease, or structural urinary tract abnormalities were considered exclusion criteria. Female patients with active pyelonephritis or symptomatic UTI at enrollment were managed per local standard before they could be re-screened for entry.

**Randomization and Intervention:** Participants were randomized in a 1:1 ratio to either:

- **Group A (Prophylaxis Group):** Received oral nitrofurantoin 50 mg once daily at bedtime, initiated at the time of randomization and continued until 37 weeks' gestation or until delivery, whichever occurred first.
- **Group B (Control Group):** Received no prophylactic antibiotic therapy but underwent routine antenatal care, including monthly urine cultures and symptom assessment.

DOI: 10.69605/ijlbpr_14.2.2025.190

A computer-generated randomization list was used. Allocation concealment was achieved through the use of sealed, opaque envelopes.

**Follow-up and Data Collection:** Both groups had scheduled monthly follow-up visits until delivery. At each visit:

- Urinalysis and urine culture were obtained.
- Maternal symptoms were assessed through standard questionnaires.
- Adherence to prophylaxis (for Group A) was evaluated via self-reported pill counts.
- Blood tests to monitor potential adverse effects (e.g., liver and renal function) were conducted every 8 weeks.

If a participant in either group developed a symptomatic UTI (dysuria, frequency, urgency), a mid-stream urine sample was collected for culture and sensitivity. Treatment was initiated as per local antibiotic guidelines, and prophylaxis was paused until completion of the therapeutic course in Group A.

**Outcome Measures**

1. **Primary Outcome:** Incidence of recurrent UTIs during the study period, defined as at least one episode of symptomatic UTI confirmed by urine culture after randomization.
2. **Secondary Outcomes:**
   - Incidence of asymptomatic bacteriuria.
   - Maternal complications (e.g., pyelonephritis, hospitalization).
   - Neonatal outcomes (gestational age at delivery, birth weight, Apgar scores).
   - Safety outcomes (adverse drug reactions, development of antibiotic resistance in isolated pathogens).

**Statistical Analysis:** facts were entered and analyzed using SPSS model 27 (IBM Corp.). Baseline characteristics had been in comparison the usage of the chi-square take a look at for particular variables and impartial t-assessments for non-stop variables. The number one final outcomes (recurrent UTIs) changed into tested the usage of relative danger (RR) estimates and ninety five% self belief periods (CIs). Kaplan-Meier survival evaluation come to be accomplished to assess time-to-first recurrence of UTI. A p-cost < zero.05 come to be taken into consideration statistically wonderful.

## RESULTS

**Overview of Study Population:** A total of 260 pregnant women were screened, and 200 met the inclusion criteria (Figure 1). The primary reasons for exclusion (n=60) were existing UTI requiring treatment at enrollment (n=25), allergy or intolerance to nitrofurantoin (n=20), or refusal to participate (n=15). Of the 200 participants, 100 were randomized to the prophylaxis group (Group A) and 100 to the control group (Group B). The flow diagram of participant enrollment and follow-up is presented in **Figure 1**

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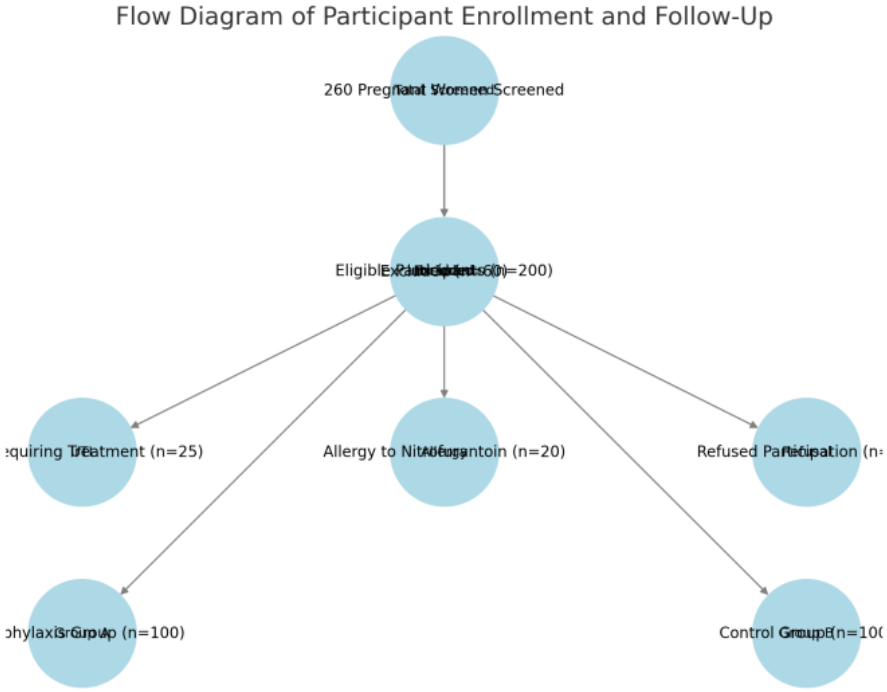
**(Figure 1: Flow diagram of participant enrollment, allocation, follow-up, and analysis)**




**Baseline Characteristics:** Baseline demographic and medical traits have been comparable between the organizations (table 1). The suggest maternal age was 28.five ± four.2 years, and the median gestational age at randomization turned into sixteen weeks. history of preceding recurrent UTIs averaged 2.6 episodes in the past

DOI: 10.69605/ijlbpr_14.2.2025.190

yr. There were no sizable variations in socio-demographic variables, obstetric history, or risk elements consisting of diabetes mellitus or smoking repute.

**Table 1. Baseline Characteristics Of Study Participants**

| Characteristic | Group A (n=100) | Group B (n=100) | p-value |
|---|---|---|---|
| Maternal Age (years, mean ± SD) | 28.7 ± 4.3 | 28.3 ± 4.1 | 0.56 |
| Gestational Age (weeks, mean) | 16.0 | 16.1 | 0.72 |
| Previous UTI Episodes (mean) | 2.7 | 2.5 | 0.63 |
| Diabetes Mellitus (%) | 8 (8%) | 10 (10%) | 0.62 |
| Smoking (%) | 2 (2%) | 1 (1%) | 0.56 |

(SD: Standard Deviation; UTI: Urinary Tract Infection)

**Incidence of Recurrent UTI:** During the follow-up period, the incidence of recurrent UTIs was significantly lower in Group A compared to Group B (15% vs. 32%, respectively; $p<0.05$). The time-to-first recurrence of UTI was also longer in Group A, as illustrated by the Kaplan-Meier curves in **Figure 2**.

**(Figure 2: Kaplan-Meier curves showing time-to-first recurrence of UTI in Group A vs. Group B.)**

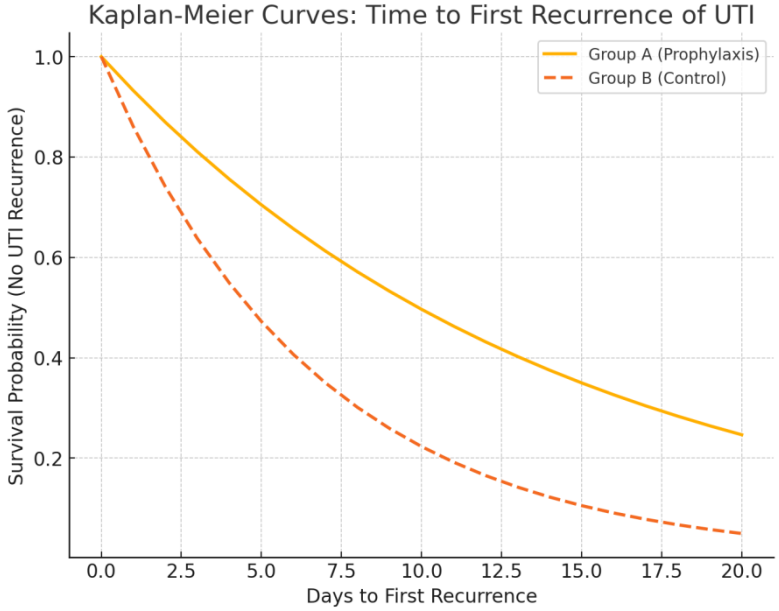



**TABLE 2. INCIDENCE OF RECURRENT UTIS AND ASYMPTOMATIC BACTERIURIA**

| Outcome | Group A (n=100) | Group B (n=100) | p-value |
|---|---|---|---|
| Recurrent UTI (% of group) | 15 (15%) | 32 (32%) | 0.01 |
| Asymptomatic Bacteriuria at ≥1 visit | 12 (12%) | 25 (25%) | 0.02 |

The rates of asymptomatic bacteriuria were also markedly lower in the prophylaxis group, with 12% of Group A participants experiencing at least one episode compared to 25% in Group B ($p<0.05$) (Table 2).

**Maternal and Neonatal Outcomes:** Maternal complications such as pyelonephritis and hospitalization did not differ significantly between the two groups (Table 3). Mean gestational age at delivery was comparable (38.2 ± 1.2 weeks in Group A vs. 38.1 ± 1.3 weeks in Group B, $p=0.71$), as were mean birth weights (3,100 ± 450 g vs. 3,050 ± 430 g, $p=0.65$). There were no statistically significant differences in neonatal Apgar scores at 1 minute or 5 minutes. No serious adverse reactions directly attributable to nitrofurantoin were reported.

**Table 3. Maternal And Neonatal Outcomes**

| Outcome | Group A (n=100) | Group B (n=100) | p-value |
|---|---|---|---|
| Pyelonephritis (%) | 2 (2%) | 4 (4%) | 0.40 |
| Hospitalization (%) | 3 (3%) | 5 (5%) | 0.47 |
| Gestational Age at Delivery | 38.2 ± 1.2 weeks | 38.1 ± 1.3 weeks | 0.71 |
| Birth Weight (g, mean ± SD) | 3100 ± 450 | 3050 ± 430 | 0.65 |

DOI: 10.69605/ijlbpr_14.2.2025.190

| | | | |
|---|---|---|---|
| Apgar Score (1 min, mean ± SD) | 7.8 ± 0.5 | 7.9 ± 0.6 | 0.34 |
| Apgar Score (5 min, mean ± SD) | 8.9 ± 0.4 | 8.8 ± 0.5 | 0.25 |

No participant withdrew due to severe adverse effects of prophylaxis, and self-reported compliance in Group A exceeded 90% across the duration of the study.

## DISCUSSION

Our data show that prophylactic nitrofurantoin at low-dose continuous therapy is effective in limiting the occurrence of recurrent UTIs during pregnancy in women who have a history of several previous UTIs, confirming the working hypothesis that prophylaxis has positive effects throughout pregnancy. The substantial decrease in both symptomatic and asymptomatic infections is consistent with prior studies in non-pregnant individuals, when sustained antibiotic prophylaxis was associated with fewer recurrences of UTIs [1,2]. While research has established putative risks of long-term antibiotic exposure, including resistance among microorganisms and infrequent adverse reactions [9], our trial showed that nitrofurantoin was well tolerated with no adverse maternal or neonatal effects.

These findings eliminate an important knowledge gap. While previous guidelines have recommended screening for asymptomatic bacteriuria and treating symptomatic infection during pregnancy, comparatively few randomized trials have addressed the usefulness of prophylaxis for recurrent UTI specifically [3,7]. Since pregnant women have increased susceptibility to complications from UTIs, the findings highlight the importance of the application of a focused prophylactic approach among high-risk patients. Notably, current guidelines typically advise against routine use of nitrofurantoin close to term because of the theoretical risk of neonatal hemolyticanemia [10]. Our study protocol stopped prophylaxis at 37 weeks, which avoided this theoretical risk.

Remarkably, a lower proportion of asymptomatic bacteriuria was seen in women on prophylaxis, which may prevent silent progression to pyelonephritis. This component is very relevant, given the fact that asymptomatic bacteriuria is a 20–30% risk of progressing to a symptomatic infection when not treated during pregnancy [4]. In addition, the optimal maternal and neonatal outcomes—manifested through equivalent gestational age, birth weights, and Apgar scores—verify that low-dose prophylaxis did not interfere with pregnancy outcome, reinforcing yet again its safety profile [5,11].

However, there are some limitations that must be highlighted. We considered a single hospital population, which limits generalizability of the findings to other populations. The short period of prophylaxis discontinuation (37 weeks) may fail to identify late-onset UTIs. It is possible to study other antibiotic drugs and dose regimens or evaluate cost-effectiveness of the prophylaxis in this pregnant population subset [3,6,12]. Moreover, extended follow-up after delivery would be useful to evaluate the possible development of antibiotic-resistant strains [8,9].

In summary, our research presents strong evidence supporting the administration of continuous low-dose nitrofurantoin to avoid recurrent UTIs during pregnancy. The results form the basis for revising clinical practice guidelines, with the suggestion that prophylaxis can be a safe and efficient means in avoiding maternal morbidity due to recurrent infection.

## CONCLUSION

This randomized controlled trial confirms the safety and efficacy of prophylactic low-dose nitrofurantoin for the prevention of recurrent UTIs in pregnancy. The patients who were on continuous prophylaxis showed significantly fewer symptomatic and asymptomatic infections without additional maternal or neonatal complications. These results highlight the potential for prophylactic targeted interventions to enhance outcomes in pregnancy and to decrease the UTI burden. Inclusion of prophylaxis in routine care for pregnant women at risk could be a significant step in prenatal care, subject to additional investigation of alternative regimens and long-term effects on antibiotic resistance.

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