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# Randomized Clinical Trail of Pregabalin Versus Montelukast in the Management of Uremic Pruritus in Hemodialysis Patients

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## Abstract

Many patients with chronic kidney (CKD) disease experience uremic pruritus (UP), which lowers quality of life. The intensity of UP varies and can cause anything from occasional pain to total restlessness during the day or night. this trial aimed to compare the efficacy of pregabalin and montelukast in uremic pruritus among CKD undergoing hemodialysis. For four weeks, this was a randomize prospective- intervention trial. patients with end-stage renal disease, between the ages of 30 and 75, been on hemodialysis at least one year and persistently severe pruritus had been included. Patients were split into Group P (n=25) receiving 50 mg of pregabalin and Group M (n=25) receiving 10 mg of montelukast. Every week, the effectiveness of the medications was evaluated using a numeric rating scale (NRS) and a 5D itch score. Compared to baseline, montelukast and pregabalin reduce 5-D scale ($p<0.05$). Between the two medications, no noticeable distinctions were seen ($p>0.05$). the study concluded that montelukast and pregabalin medication, have a positive effect on reducing UP while there were no significant differences observed between the two drugs.

**Keyword: Dialysis, Chronic Kidney Disease, Montelukast, Pregabalin, Uremic Pruritus**

## Introduction

Chronic kidney disease (CKD) is considered as abnormalities in the structure or function of the kidneys that persist for ≥3 months and have an impact on one's health. It can be attributed to any disorder that disrupts the typical chronic kidney disease (CKD) is considered as abnormalities in the structure or function of the kidneys that persist for ≥3 months and have an impact on one's health. It can be attributed to any disorder that disrupts the typical structure and function of the kidney [(1)]. CKD classifications are determined by assessing the glomerular filtration rate (GFR) and the presence of albuminuria [(2, 3)]. The frequency of advanced chronic kidney disease (CKD), classified explicitly as CKD G4-G5 (with an estimated glomerular filtration rate of less than (30 mL/min/1.73 $m^2$) [(4, 5)]. Issues associated with chronic kidney disease (CKD) include anemia, hypertension, cardiovascular issues, salt and water retention, mineral bone diseases, electrolyte disorders, and metabolic acidosis, as well as uremic symptoms that includes nausea, vomiting, weight loss, difficulty concentrating and fatigue. Pruritus is a prevalent and troublesome symptom in individuals with kidney disease, and nephrologists significantly underestimate its frequency. [(6, 7)]. Pruritus is a bothersome condition frequently observed in patients suffering from chronic kidney disease (CKD), end - stage renal disease (ESRD), and individuals undergoing dialysis. [(7)]. It unpleasantly affects the quality of life (QOL) of these patients [(8)]. The terminology has recently been updated from "uremic pruritus" to “CKD-associated pruritus (CKDaP) due to the non-linear relationship between itch and the degree of uremia”. [(9, 10)]. Empirical research in real-life settings suggests that CKD-aP impacts approximately “80% of ESKD patients undergoing hemodialysis (HD), with around “40% feeling moderate to severe itch” [(11)]. The pathogenesis of pruritus in CKD is multiple possibilities have been suggested; like xerosis, calcium-phosphate product, divalent ions, hyperparathyroidism and interleukin-31. Apart from this, the clearance of pruritogenic substances and adequacy of dialysis could reduce the severity of pruritus [(12, 13)].Conventional treatments including topical calcineurin inhibitors, capsaicin, menthol, cannabinoid agonists, Antihistamines, and leukotriene antagonists impact itch transmission in the peripheral nervous system. On the other hand, μ opioid receptor antagonists, antidepressants, and antiepileptics like pregabalin and gabapentin work centrally [(14, 15)]. Pregabalin is a derivative of gamma-aminobutyric acid that binds to voltage-gated calcium channels to reduce the effects of substance P, excitatory neurotransmitters, and peptides linked to the calcitonin gene.

The effects of pregabalin are responsible for lowering neuropathic pain and anxiety and managing epilepsy. However, the precise mechanism of pregabalin to reduce itch sensation has yet to be understood. [13]. Pregabalin is associated with transient mild to moderate adverse effects which are dose dependent. Dizziness and somnolence. Other less common adverse effects are peripheral edema, blurred vision, dry mouth, inability to concentrate and weight gain [16].

Montelukast is a medication that blocks the action of leukotriene receptors. It is commonly prescribed for conditions such as eosinophilic peritonitis, allergic rhinitis, atopic dermatitis, and asthma. Montelukast can inhibit the production of substances that cause inflammation, including the substance P, which functions as a neurotransmitter in UP. These findings can elucidate the antipruritic mechanism of montelukast for uremic pruritic (UP). [17-20]. It is essential to mention that this treatment is highly safe, with limited interactions with other medications and few adverse effects [12].An-Yu Cheng *et al.* had been summarized the way to accurately diagnose and describes the latest treatment options of uremic pruritus showed that Pregabalin and gabapentin have been found in multiple clinical trials to be statistically effective in reducing the degree of pruritus in patients with uremic pruritus. while 80 hemodialysis patients who received 10 mg of montelukast daily for 30 days participated in a randomized, double-blind controlled experiment, and the results showed that montelukast considerably reduced pruritus when compared to the placebo group. [15] Carlos Santos-Alonso *et al*. had been showed that pregabalin (25mg daily in PD patients and 25mg post-HD in HD patients) can obtain comparable results in uremic pruritus with better tolerance than gabapentin. On the other hand, at daily doses of 10 mg, montelukast significantly reduced C-reactive protein levels in uremic pruritus; hence, its effects may be attributed to its anti-inflammatory properties. Notably, it is an extremely safe treatment with little side effects and interactions with other drugs. [12]The aim of this study compares and assesses the efficacy of pregabalin and montelukast in the treatment of uremic pruritus in hemodialysis patients. Our goal is to improve the quality of life for hemodialysis patients and manage uremic pruritus more effectively and individually through this research.

## Methods

### *The ethical concern and patient preparation*

The study was a prospective- intervention clinical trial. The research proposal was verified by Research Ethics Committee of the Medicine college, Baghdad university (Number: 03-8 dated 13 March 2024) and the Baghdad Medical City Complex (Number: 45468 dated 29 November 2023) Before their enrollment in the trial, every patient provided their informed consent. the eligible patients were included in the study and they were allocated into two groups.

### *Inclusion and exclusion criteria*

### *Inclusion criteria*

Patients on hemodialysis therapy (HD) for 3 months or more with uremic pruritus (continued symptoms despite adequate dialysis, optimization of metabolic parameters such as serum phosphorus, parathyroid hormone, serum calcium).Single-pool adequacy of dialysis (spKt/V), remains the best studied measure of dialysis adequacy globally. Among HD patients, values of spKt/V less than 1.2 are associated with increased mortality. The spKt/V was calculated as follows:

$spKt/V = -\ln(R - 0.008 \times t) + (4 - 3.5 \times R) \times UF/W$

where R is the ratio of pre- to post-HD concentration of blood urea nitrogen (BUN), t is dialysis session length (in hours), UF is amount of ultrafiltration (L) during the given HD session, and W is post-HD weight (kg) [21].

Exclusion Criteria:

- Elevated intact parathyroid hormone (iPTH) >600pg/ml [22]
- High serum phosphorus >5.5 mg/dl [12]
- Patients with liver disease [23]
- Current itching with dermatologic disease other than uremic pruritus [23]

### *Study protocol*

Of 426 hemodialysis patients referred to Baghdad Teaching Hospital/Iraqi Center of Dialysis in 2024, 144 patients were diagnosed with uremic pruritus. From this group, a selection of °° patients was made. All patients in our study exhibited uniformity in the frequency and technique of dialysis.The eligible patients (both genders, aged 30 to 75 years) (n=55) were allocated into two groups randomly by a simple lottery method, Group P and Group M. Group P consisted of (n=28) patients who received a dose of 50 mg pregabalin tablets every other day. In contrast, Group M consisted of (n=27) patients who received a daily dose of 10 mg montelukast tablets. This study was conducted over 4 weeks follow-up every week; baseline (before treatment), week1, week2, week3, week4 (Figure 1). This study started on December 2023 till March 2024 .

### *Outcome measures*

The effectiveness of the medications was evaluated every week over four weeks using the 5-D itch scale, a concise questionnaire that may be easily completed its assesses 5 domains of itch and effect "(degree, duration, direction, body distribution of itch, and disability due to itch).[24, 25] The 5-D scores vary between 5 (indicating no pruritus) and 25 (representing the most severe pruritus). The numeric rating scale (NRS) is a one-dimensional scale of 11 points, calculated using the

provided equation. [26]NRS=-2.31+0.52× (5-D itch scale)Scoring zero points indicates the absence of pruritus (itching), whereas scoring 1-3 on the Numeric Rating Scale (NRS) indicates mild itch. Scoring 4-6 points is considered moderate itch, 7-8 points is classified as severe itch, and scoring 9 points or more is regarded as severe pruritus. [27].

***Statistical analysis***

Analysis of data was carried out using the available statistical package of SPSS-26(Statistical Package for Social Sciences-version 26). Within each group (group P or M) changes in 5-D score and NRS with respect to baseline were compared using paired t-test. While Comparisons between the two groups (Group P versus group M) of each parameter (5-D score and NRS) were done by unpaired t-test. Statistical significance was considered whenever the P value was equal to or less than 0.05.

## Result

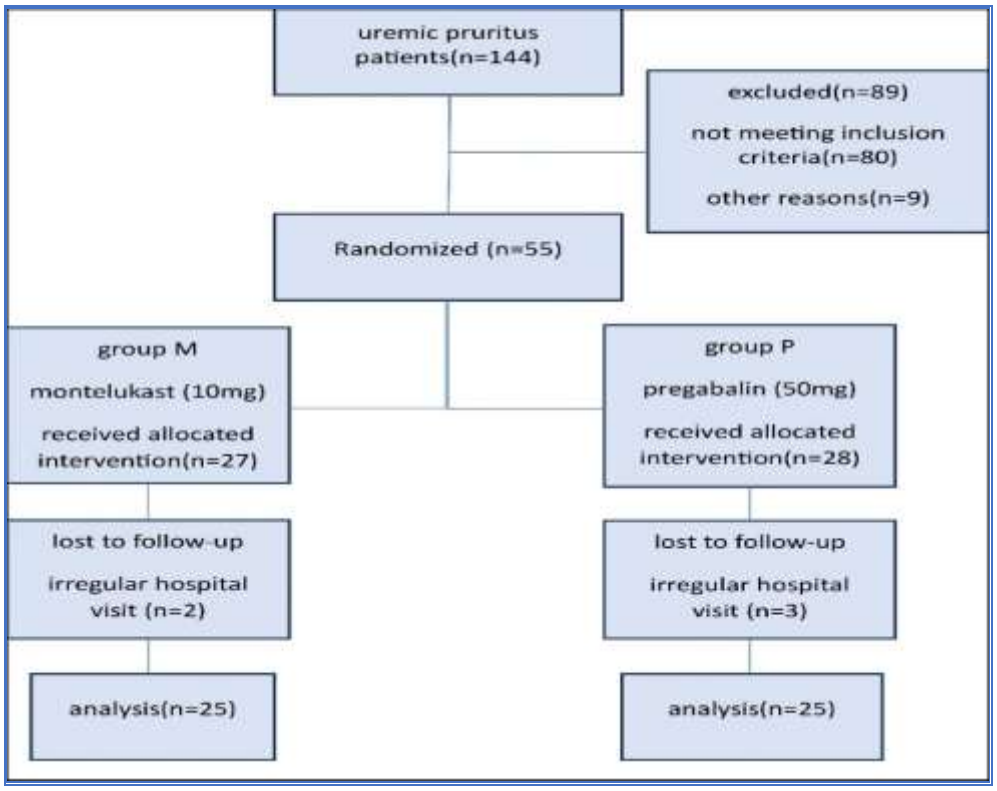


**Figure 1. Flowchart of study design**

The basic characteristics of the patients is summarized in Table 1

**Table 1. Patient characteristics were comparable in both groups at baseline**

| Criteria | | Montelukast (10mg/day) (n=25) | Pregabalin (50mg/every other day) (n=25) | P value |
|---|---|---|---|---|
| Age (years) | | 55.76±11.50 | 54.80±10.78 | 0.76 |
| Gender | M | 8 (42.1%) | 11 (57.9%) | 0.38 |
| | F | 17 (54.8%) | 14 (45.2%) | |
| Dry weight (Kg) | | 76.40±19.46 | 73.08±17.21 | 0.52 |
| PO4(mg/dL) | | 4.58±1.15 | 4.72±1.07 | 0.65 |
| PTH (pg./mL) | | 377.23±180.15 | 279.68±215.07 | 0.08 |
| Hb (g/dL) | | 9.88±1.55 | 9.91±1.75 | 0.95 |
| S. ferritin (mcg/L) | | 374.36±102.82 | 378.78±179.42 | 0.91 |
| Ca (mg/dL) | | 7.88±1.91 | 7.65±2.31 | 0.69 |
| Dialysis adequacy | | 1.09±0.34 | 1.11±0.34 | 0.82 |

*Data expressed as mean± standard deviation (SD), chi-square for gender and unpaired t-test were used to determine the differences between the two groups for continuous variable. Dry weight: The weight after dialysis. There was no significant difference (p>0.05) between the two groups in patient characteristics

In group P, at baseline (before treatment) all the patients had moderate to severe itching (NRS) (moderate 8 patients; severe 14 patients; very severe 3 patients) and no patients with mild itching. After 4 weeks of treatment, all patients became mild as shown in Table 2

In group M, at baseline (before treatment) all the patients had moderate to severe itching (NRS) (moderate 4 patients; severe 18 patients; very severe 3 patients) and no patients with mild itching. After 4 weeks of treatment, all patients became mild as shown in Table 3

**Table 2. Effect of treatment with Montelukast (10mg/day) in hemodialysis patients with uremic pruritus**

| n=25 | Baseline | Week1 | Week2 | Week3 | Week4 | p-value |
|---|---|---|---|---|---|---|
| 5-D score | 19.44±2.21 | 10.88±3.45 | 8.96±2.85 | 7.88±2.60 | 6.60±2.02 | 0.00 |
| NRS | 7.81±1.15 | 3.34±1.79 | 2.34±1.48 | 1.78±1.35 | 1.12±1.05 | 0.00 |

Values are expressed as mean± stander deviation (SD). n=number of patients. Data analyzed by paired t-test. This Table ($p<0.05$) show a significant difference in the 5-D itching score and NRS in group M after 4 weeks of treatment from the baseline score.

**Table 3. Effect of treatment with Pregabalin (50mg/every other day) in hemodialysis patients with uremic pruritus**

| n=25 | Baseline | Week1 | Week2 | Week3 | Week4 | p-value |
|---|---|---|---|---|---|---|
| 5-D score | 18.96±2.60 | 9.76±3.58 | 8.56±2.94 | 8.56±2.94 | 6.00±1.89 | 0.00 |
| NRS | 7.54±1.35 | 2.76±1.86 | 2.14±1.53 | 1.24±1.12 | 0.81±0.98 | 0.00 |

Values are expressed as mean± stander deviation (SD). n=number of patients. Data analyzed by paired t-test. This Table ($p<0.05$) show a significant difference in the 5-D itching score and NRS in group P after 4 weeks of treatment from the baseline score.

**Table 4. Comparison of the effects of Montelukast and Pregabalin on 5-D score**

| | Montelukast (10mg/day) (n=25) | Pregabalin (50mg/every other day) (n=25) | P-value |
|---|---|---|---|
| WB | 19.44±2.219 | 18.96±2.60 | 0.48 |
| W1 | 10.88±3.45 (44%) | 9.76±3.58 (49%) | 0.26 |
| W2 | 8.96±2.85 (54%) | 8.56±2.94 (55%) | 0.62 |
| W3 | 7.88±2.60 (59%) | 6.84±2.15(64%) | 0.13 |
| W4 | 6.60±2.02 (66%) | 6.00±1.89 (68%) | 0.28 |

Values are expressed as mean± stander deviation (SD). n=number of patients. WB= baseline week. Data analyzed by independent t-test. There was no significant difference ($p>0.05$) between the two groups in the 5-D score after four weeks of treatment Figure 2.

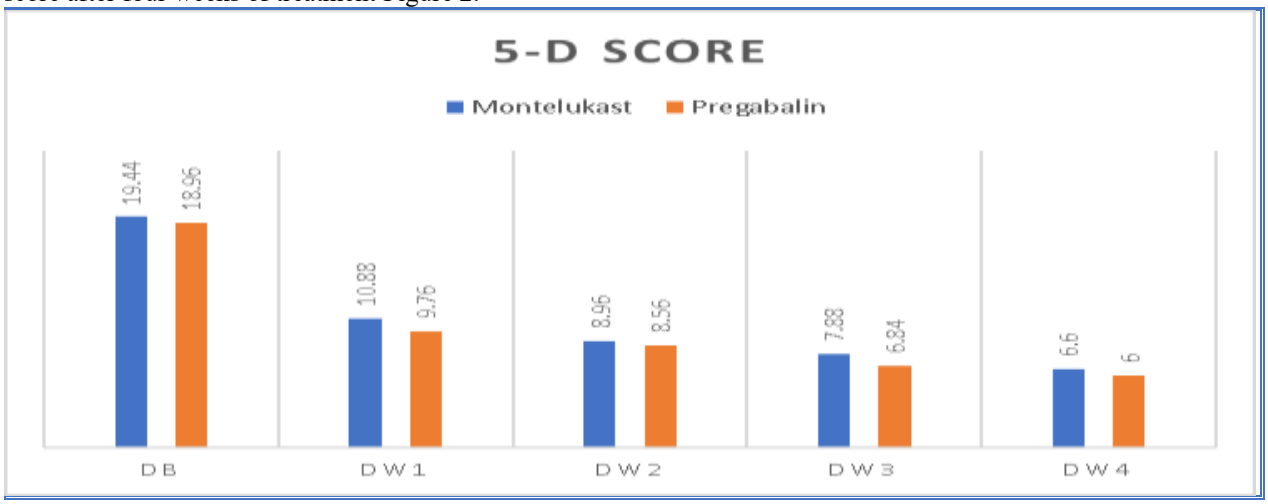


**Figure 2. Comparison of the effects of Montelukast and Pregabalin on 5-D score.**DB=baseline, DW1=5-D score in first week, DW2=5-D score in second week, DW3=5-D score in third week, DW4=5-D score in fourth week.

**Table 5. Comparison of the effects of Montelukast and Pregabalin on NRS**

| | Montelukast (10mg/day) (n=25) | Pregabalin (50mg/every other day) (n=25) | P-value |
|---|---|---|---|
| WB | 7.81±1.15 | 7.54±1.35 | 0.46 |
| W1 | 3.34±1.79 | 2.76±1.86 | 0.26 |
| W2 | 2.34±1.48 | 2.14±1.53 | 0.62 |
| W3 | 1.78±1.35 | 1.24±1.12 | 0.13 |
| W4 | 1.12±1.05 | 0.81±0.98 | 0.28 |

Values are expressed as mean± stander deviation (SD). n=number of patients. WB= baseline week. Data analyzed by independent t-test. There was no significant difference (p>0.05) between the two groups in NRS after four weeks of treatment Figure 3.

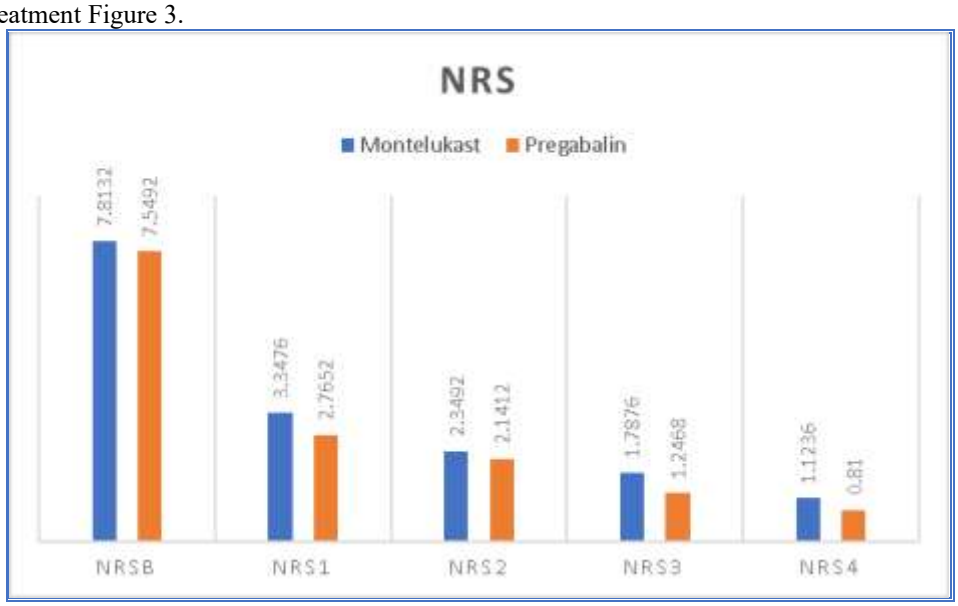


**Figure 3. Comparison of the effects of Montelukast and pregabalin on NRS.**NRSB=NRS in baseline, NRS1= NRS in first week, NRS2= NRS in second week, NRS3= NRS in third week, NRS4= NRS in fourth week.

## Discussion

Although several theories about pathogenesis of CKD-ap, such as the inflammatory processes and the accumulation of uremic toxins, have been proposed, the exact mechanism of pruritus in uremic patients is not yet fully understood, to elucidate the underlying mechanisms further research is still needed therefor there are many drugs use in management among of them pregabalin and montelukast [(28)]pregabalin and montelukast were highly efficacious in reducing the severity of uremic pruritus. Table 2, The findings demonstrated a substantial decrease of 66% (p<0.05) in the 5-D score of the montelukast group after four weeks of treatment. The Numeric Rating Scale (NRS) showed a substantial decrease after four weeks of treatment, going from a severity level of 7.8 to a mild level of 1.1 (p<0.05). Montelukast binds to cysteinyl leukotriene receptors specific for leukotrienes D4 and E4. This binding inhibits the subsequent inflammatory responses triggered by these leukotrienes. The presence of these receptors on mast cells may account for the antipruritic activity of montelukast. [(29)]Mehdi Mahmudpour *et al*. The impact of montelukast and placebo was tested in eighty patients suffering from uremic pruritus. The study showed that administering montelukast 10 mg/d to individuals undergoing hemodialysis can effectively alleviate the intensity of uremic pruritus. [(30)]Chao-qing Gao and colleagues conducted a systematic review and meta-analysis to offer clinical evidence supporting the effectiveness of montelukast for uremic pruritus (UP) in hemodialysis patients by Seven electronic literature databases [(31)]Table 3, The findings indicated that the 5-D score of pregabalin group saw a substantial decrease of 68% after four weeks of treatment (p<0.05). The Numeric Rating Scale (NRS) showed a substantial decrease after four weeks of treatment, going from a severity level of 7.5 to a mild level of 0.8 (p<0.05).The mechanism of action of pregabalin in treating uremic pruritus is believed to entail the inhibition of primary afferent neurons' release of calcitonin gene-related peptide, a mediator of itching, and the negative control of voltage-gated calcium channels' alpha 2 delta subunit. It has also been hypothesized the anti-itch properties of this drug may be mediated through the modulation of μ-opioid receptors (MORs).[(32)].

A study conducted by A. Ravindran *et al*. examined the impact of gabapentin 100 mg and pregabalin 25 mg on a group of twenty-one patients suffering from uremic pruritus. The study showing that both

gabapentin (100 mg) and pregabalin (25 mg) effectively alleviate pruritus in dialysis patients compared to the baseline (no medication) and pregabalin was associated with fewer side effects than gabapentin [13]Khaled F. El Mulla *et al*. compared Narrow band-ultraviolet B (NB-UVB) and pregabalin to assess their safety and effectiveness in treating CKD-AP. The study demonstrated that NB-UVB and pregabalin are both efficacious choices for treating CKD-AP and phototherapy had rapid onset of relief of pruritus, fewer adverse effects, and delayed recurrence of pruritus after cessation of therapy but noncompliant for the patients [33]By comparing the effects of montelukast and pregabalin on 5-D score (Table 4), and on NRS (Table 5), Both show no significant differences. ($p>0.05$) in the therapy of uremic pruritus in hemodialysis patients. The pregabalin and montelukast both of them effective in management of CKD-ap.A study by Christopher Boehlke *et al*. evaluated the efficacy of various pharmaceutical interventions in the prevention or treatment of pruritus when compared to a placebo, no treatment, or an alternative treatment. The results showed that various interventions (such as GABA analogs, kappa-opioid receptor agonists, cromolyn sodium, montelukast, fish oil/omega-3 fatty acids, and topical capsaicin) were effective in treating uremic pruritus when compared to a placebo. GABA analogues were the most effective in reducing pruritus. [34]

## Conclusion

This study has shown that montelukast 10 mg daily and pregabalin 50 mg even other day effectively alleviate itching in dialysis patients with chronic kidney disease (CKD) who continue to have symptoms. These medications improved pruritus compared to the baseline condition without any therapy. No notable disparities were detected between the two medications. The choice between these options should be individualized based on the patient's specific symptoms, overall health, and response to treatment.

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## Ethical Statements

The research proposal was verified by Research Ethics Committee of the Medicine college, Baghdad university (Number: 03-8 dated 13 March 2024) and the Baghdad Medical City Complex (Number: 45468 dated 29 November 2023).

## Conflict of Interest

The authors declared no conflicts of interest.

## Author Contributions

The authors confirm contribution to the paper as follows: study conception and design: Samara Mowafaq Ali, data collection: Ruba Ahmed Najeeb, analysis and interpretation of results: Ruba Ahmed Najeeb, Samara Mowafaq Ali, draft manuscript preparation: Ruba Ahmed Najeeb, Samara Mowafaq Ali. All authors reviewed the results and approved the final version of the manuscript.

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# تجربة سريرية عشوائية لبريجابالين بالمقارنة مع مونتيلوكاست لعلاج الحكة البولية لمرضى غسيل الكلى

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**الخلاصة**

يعاني العديد من مرضى الكلى المزمن من الحكة البولية ، مما يخفض من جودة الحياة. تختلف شدة الحكة البولية من الألم العرضي إلى الأرق التام في اي وقت من اليوم. تهدف هذه الدراسة إلى مقارنة فعالية بريجابالين ومونتيلوكاست في الحكة البولية بين مرض الكلى المزمن الذي يخضعون لغسيل الكلى.و مدة الدراسة أربعة أسابيع ، كانت هذه تجربة عشوائية ذات تداخل مستقبلي. الدراسة شملت المرضى الذين يعانون من مرض الكلى في المرحلة النهائية ، تتراوح أعمارهم بين ٣٠ و ٧٥ عاما ، يخضعون لغسيل الكلى لمدة عام على الاقل مع وجود حكة شديدة مستمرة. تم تقسيم المرضى إلى المجموعة P (ن = ٢٥) تلقي ٥٠ ملغ من بريجابالينبين والمجموعة M (ن = ٢٥) تلقي ١٠ ملغ من مونتيلوكاست. كل اسبوع ، يتم تقييم فعالية الأدوية باستخدام مقياس تصنيف رقمي (NRS) ودرجة حكة( ( D.٥بالمقارنة مع ما قبل العلاج، يقلل مونتيلوكاست وبريجابالين من مقياس ٥ .D(p<0.05) بين الدواءين ، لم يلاحظ أي تمييز ملحوظ . (p>0.05) خلصت الدراسة إلى أن دواء مونتيلوكاست وبريجابالين لهما تأثير إيجابي على الحد من الحكة البولية بينما لم تكن هناك فروق ذات دلالة إحصائية بين العقارين.

**الكلمات المفتاحية: غسيل الكلى، أمراض الكلى المزمنة، مونتيلوكاست ، بريجابالين ، الحكة البولية.**