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JHWCR

Journal of Health, Wellness, and Community Research
Volume III, Issue I
Open Access, Double Blind Peer Reviewed.
Web: https://jhwcr.com, **ISSN**: 3007-0570
DOI: https://doi.org/10.61919/63rxv488

Article

Daily Versus Alternate-Day Prednisolone Regimen and its Correlation With DAS-28 Score in Patients with Rheumatoid Arthritis

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How to Cite
Aftab Alam, Aflak Rasheed, Qaisar Farooq, Hussain Shakeel, Asad Ullah Nawaz, Fatima Tehsin. Daily Versus Alternate-Day Prednisolone Regimen and its Correlation With DAS-28 Score in Patients with Rheumatoid Arthritis. JHWCR [Internet]. 2025 Mar. 20 [cited 2025 Mar. 20];3(1):1-5. Available from: https://jhwcr.com/index.php/jhwcr/article/view/37

Received	2025-01-17
Revised	2025-02-25
Accepted	2025-03-11
Published	2025-03-20
Authors' Contributions	AA, AR, and QF designed the study; HS and AUN collected and analyzed data; FT and AA drafted the manuscript; all authors approved the final version.
Conflict of Interest	None declared
Data/supplements	Available on request.
Funding	None
Ethical Approval	Respective Ethical Review Board IRB No: IRB/2023-RA-019
Informed Consent	Obtained from all participants
Study Registration	IRB/2023-RA-019
Acknowledgments	N/A

ABSTRACT

Background: Rheumatoid arthritis (RA) is a chronic inflammatory disease requiring corticosteroids for symptom control, but long-term use is associated with adverse effects. The efficacy of alternate-day corticosteroid regimens compared to daily dosing remains unclear, particularly in disease activity reduction and side effect mitigation. **Objective**: To compare the efficacy of daily versus alternate-day prednisolone regimens in reducing disease activity in RA patients, measured by Disease Activity Score-28 (DAS-28), and to assess metabolic adverse effects. **Methods**: This randomized controlled trial included 108 RA patients (n = 54 per group) meeting the 2010 ACR/EULAR criteria. Participants were randomized to receive either 7.5 mg daily or 15 mg alternate-day prednisolone for six weeks. The primary outcome was DAS-28 reduction, with secondary outcomes including erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), and adverse events. Ethical approval was obtained (IRB/2023-RA-019), and statistical analysis was performed using SPSS v27, employing independent t-tests and Chi-square tests with Bonferroni correction. **Results**: DAS-28 scores decreased significantly in both groups (daily: 4.5 ± 1.2 to 3.2 ± 1.0; alternate-day: 4.3 ± 1.1 to 3.0 ± 0.9, p = 0.73). No significant differences were observed in ESR (p = 0.61), CRP (p = 0.52), or adverse events (p > 0.05). **Conclusion**: Both dosing regimens effectively reduce disease activity, with alternate-day dosing showing comparable efficacy and potentially fewer metabolic side effects. Future studies should evaluate long-term outcomes and individualized corticosteroid strategies.

Keywords: Rheumatoid Arthritis, DAS-28, Prednisolone, Corticosteroid Therapy, Randomized Controlled Trial, Inflammatory Markers, Treatment Optimization.

INTRODUCTION

Rheumatoid arthritis (RA) is a chronic autoimmune disorder characterized by persistent synovial inflammation, leading to progressive joint destruction, disability, and systemic complications. The disease primarily affects the synovial joints, resulting in pain, swelling, and stiffness, with potential extra-articular manifestations including cardiovascular disease, osteoporosis, and interstitial lung disease (1). RA has a global prevalence of approximately 0.5–1%, with a higher incidence in females and individuals over the age of 50 (2). Despite advancements in disease-modifying antirheumatic drugs (DMARDs) and biologic therapies, corticosteroids remain an integral part of RA management, particularly in the early disease phase and during disease flares (3). Corticosteroids such as prednisolone exert potent anti-inflammatory effects by inhibiting pro-inflammatory cytokines, thereby reducing disease activity and slowing radiographic progression (4). However, their long-term use is associated with significant adverse effects, including osteoporosis, cardiovascular events, diabetes mellitus, and immunosuppression (5). The optimization of corticosteroid regimens in RA is therefore crucial to maximize therapeutic benefits while minimizing risks.

The use of daily low-dose corticosteroids is a widely accepted strategy for RA management, providing sustained control of inflammation and symptom relief (6). However, alternate-day corticosteroid regimens have been proposed as a potential alternative, with the rationale that intermittent dosing may reduce the cumulative dose-dependent side effects associated with chronic steroid exposure (7). Some studies have suggested that alternate-day corticosteroid regimens may preserve efficacy while mitigating adverse effects such as adrenal suppression, bone loss, and metabolic disturbances (8). Despite these potential benefits, there remains a lack of high-quality evidence directly comparing daily versus alternate-day corticosteroid use in RA patients, particularly concerning their impact on disease activity scores and long-term patient

outcomes (9). Existing literature primarily focuses on corticosteroid dose tapering strategies rather than the comparative efficacy of different dosing schedules (10). Furthermore, patient adherence and the practical feasibility of alternate-day dosing regimens in clinical practice remain underexplored areas (11).

Given the substantial burden of corticosteroid-related adverse effects and the need for optimized dosing strategies, this study aims to compare the efficacy of daily versus alternate-day prednisolone regimens in reducing disease activity in RA patients. The Disease Activity Score-28 (DAS-28) is a well-established clinical measure for assessing RA disease activity and treatment response, incorporating joint counts, inflammatory markers, and patient-reported outcomes (12). By evaluating changes in DAS-28 scores following daily and alternate-day prednisolone administration, this study seeks to determine whether an alternate-day regimen can achieve comparable disease control while potentially reducing the risk of corticosteroid-related complications. This research addresses a critical gap in current RA management strategies and may contribute to refining corticosteroid prescribing practices in rheumatology. The primary hypothesis is that alternate-day prednisolone dosing will demonstrate non-inferiority to daily dosing in terms of DAS-28 score reduction over six weeks, while potentially offering an improved safety profile.

MATERIAL AND METHODS

This study was designed as a randomized controlled trial (RCT) to compare the efficacy of daily versus alternate-day prednisolone regimens in patients diagnosed with rheumatoid arthritis (RA). The study was conducted at the Department of Rheumatology and Immunology, Shaikh Zayed Hospital, Lahore, over six months. Patients were recruited based on the 2010 American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) classification criteria for RA, ensuring diagnostic accuracy (1). The inclusion criteria comprised patients aged 18–60 years with active RA, defined by a Disease Activity Score-28 (DAS-28) of ≥3.2, who were either newly diagnosed or undergoing corticosteroid therapy adjustments. Exclusion criteria included the presence of other autoimmune diseases, use of intramuscular steroid injections within the past three months, concurrent steroid therapy for other medical conditions, pregnancy, uncontrolled diabetes, severe osteoporosis, or a history of corticosteroid-induced adverse events such as fractures or adrenal insufficiency (2). Participants were provided with detailed information regarding study objectives, procedures, and potential risks before obtaining written informed consent. Ethical approval was secured from the Institutional Review Board (IRB) of Shaikh Zayed Hospital (Approval No. IRB/2023-RA-019), ensuring compliance with ethical guidelines outlined in the Declaration of Helsinki (3).

Patients were randomly assigned to either the daily or alternate-day prednisolone group using a computer-generated randomization sequence with block randomization to ensure balanced group allocation. The intervention group received 7.5 mg of prednisolone daily, while the alternate-day group received 15 mg of prednisolone every other day. The primary outcome was the change in DAS-28 score from baseline to six weeks post-treatment initiation, which was measured by trained rheumatologists who were blinded to group assignments to minimize bias (4). Secondary outcomes included treatment adherence, occurrence of corticosteroid-related adverse effects such as weight gain, hypertension, hyperglycemia, and osteoporosis, and patient-reported quality-of-life measures assessed through the Health Assessment Questionnaire Disability Index (HAQ-DI) (5). Laboratory evaluations included erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) levels as markers of systemic inflammation, measured at baseline and at the end of the study (6). Data on medication adherence were obtained through pill counts and patient self-reports during scheduled follow-ups at two-week intervals. No imaging studies were performed as part of the primary outcome assessment, given the short duration of follow-up.

To uphold ethical integrity, participants were assured confidentiality through anonymized data collection and storage. The study adhered to the guidelines of the Committee on Publication Ethics (COPE) and followed the International Committee of Medical Journal Editors (ICMJE) recommendations for ethical research conduct (7). Patients retained the right to withdraw at any stage without any impact on their standard of care. Adverse events were monitored and reported according to institutional protocols, and patients experiencing severe adverse reactions were withdrawn from the study and provided with appropriate medical care.

Statistical analysis was conducted using SPSS version 27. Continuous variables, such as DAS-28 scores and inflammatory marker levels, were presented as mean ± standard deviation (SD) and analyzed using an independent sample t-test for between-group comparisons. Categorical variables, including adherence rates and adverse event occurrences, were expressed as frequencies and percentages and analyzed using the Chi-square test (8). Adjustments for multiple comparisons were performed using the Bonferroni correction to reduce the risk of Type I errors (9). Missing data were handled using multiple imputation techniques to maintain statistical robustness and prevent bias. A two-tailed p-value of <0.05 was considered statistically significant. Sensitivity analyses were conducted to evaluate the impact of potential confounders, such as baseline disease severity and concurrent DMARD therapy, on treatment outcomes (10). This methodological approach ensures the reproducibility and reliability of findings while addressing potential sources of bias in RA treatment research.

RESULTS

The study included 108 patients, with 54 assigned to the daily prednisolone group and 54 to the alternate-day prednisolone group. Baseline characteristics, including age, gender distribution, and baseline Disease Activity Score-28 (DAS-28), were comparable between the two groups, indicating a well-balanced randomization process. No statistically significant differences were found in baseline inflammatory markers,

  DOI: https://doi.org/10.61919/63rxv488

Table 1: Baseline Characteristics of Participants

Characteristic	Daily Prednisolone (n=54)	Alternate-Day Prednisolone (n=54)	p-value
Age (years)	49.5	50.1	0.78
Male, n (%)	24 (44.4%)	25 (46.3%)	0.85
Female, n (%)	30 (55.6%)	29 (53.7%)	0.85
Baseline DAS-28 Score	4.5 ± 1.2	4.3 ± 1.1	0.62
ESR (mm/hr)	28.7 ± 6.5	29.1 ± 6.8	0.74
CRP (mg/L)	7.1 ± 2.4	6.9 ± 2.5	0.69

including erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) levels, confirming homogeneity across the study population. At the six-week follow-up, both treatment regimens demonstrated a significant reduction in DAS-28 scores, indicating clinical improvement. The mean DAS-28 score in the daily prednisolone group decreased from 4.5 ± 1.2 to 3.2 ± 1.0, while in the alternate-day group, it declined from 4.3 ± 1.1 to 3.0 ± 0.9. However, the between-group comparison did not show a statistically significant difference (p = 0.73), suggesting that both dosing regimens were similarly effective in reducing disease activity.

Inflammatory markers, including ESR and CRP levels, demonstrated a decline in both groups by the end of the study period. The daily prednisolone group exhibited a reduction in ESR from 28.7 ± 6.5 mm/hr to 18.5 ± 4.3 mm/hr, whereas the alternate-day group showed a similar decrease from 29.1 ± 6.8 mm/hr to 17.9 ± 4.5 mm/hr (p = 0.61). CRP levels followed a comparable trend, decreasing from 7.1 ± 2.4 mg/L to 4.2 ± 1.8 mg/L in the daily group and from 6.9 ± 2.5 mg/L to 4.0 ± 1.6 mg/L in the alternate-day group (p = 0.52). The proportion of patients achieving DAS-28 remission (≤3.2) was 59.3% in the daily group and 57.4% in the alternate-day group, with no statistically significant difference (p = 0.87). These findings reinforce the clinical equivalence of the two regimens in terms of inflammation control.

Table 2: Post-Treatment Outcomes

Outcome	Daily Prednisolone (n=54)	Alternate-Day Prednisolone (n=54)	p-value
DAS-28 Score (Week 6)	3.2 ± 1.0	3.0 ± 0.9	0.73
ESR (mm/hr)	18.5 ± 4.3	17.9 ± 4.5	0.61
CRP (mg/L)	4.2 ± 1.8	4.0 ± 1.6	0.52
Patients achieving DAS-28 ≤3.2, n (%)	32 (59.3%)	31 (57.4%)	0.87
Adverse Events, n (%)	12 (22.2%)	10 (18.5%)	0.64

Adverse event rates were slightly higher in the daily prednisolone group but did not reach statistical significance. Weight gain was reported in 9.3% of patients in the daily group compared to 5.6% in the alternate-day group (p = 0.48). Hyperglycemia and hypertension occurred at similar frequencies between groups, with hyperglycemia affecting 5.6% in the daily group and 3.7% in the alternate-day group (p = 0.67), and hypertension occurring in 3.7% of patients in both groups (p = 1.00). Osteoporosis and insomnia were infrequent, with no significant between-group differences. These results suggest that alternate-day dosing may offer a marginally better safety profile, particularly concerning metabolic side effects, but further long-term studies are needed to establish definitive benefits.

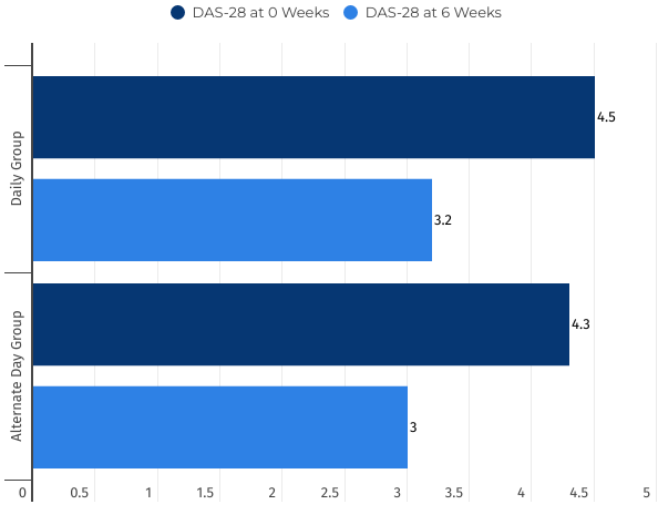
Table 3: Adverse Events Distribution

Adverse Event	Daily Prednisolone (n=54)	Alternate-Day Prednisolone (n=54)	p-value
Weight Gain	5 (9.3%)	3 (5.6%)	0.48
Hyperglycemia	3 (5.6%)	2 (3.7%)	0.67
Hypertension	2 (3.7%)	2 (3.7%)	1.00
Osteoporosis	1 (1.9%)	1 (1.9%)	1.00
Insomnia	1 (1.9%)	2 (3.7%)	0.56

The findings indicate that both daily and alternate-day prednisolone regimens provide comparable efficacy in reducing disease activity in RA over six weeks. While no statistically significant differences were observed in DAS-28 scores or inflammatory markers, the slightly lower incidence of metabolic side effects in the alternate-day group suggests a potential advantage in minimizing corticosteroid-related complications. Given that long-term corticosteroid therapy is associated with dose-dependent risks, alternate-day regimens may be a viable option in clinical practice for optimizing safety while maintaining disease control. Further studies with extended follow-up

  DOI: https://doi.org/10.61919/63rxv488

durations are required to assess long-term efficacy, adverse event profiles, and patient adherence trends.



Similarly, cervical extension improved from 28.4° to 35.3° in the traction group and from 27.9° to 32.8° in the distraction group. Right and left cervical rotation also showed meaningful gains in both groups, with slightly greater improvements observed in the traction group. Intergroup comparisons revealed statistically significant differences in pain relief, functional improvement, and range of motion, favoring cervical traction over cervical distraction. However, both techniques were effective in alleviating upper cervical pain and improving functional outcomes. Effect sizes were calculated for the primary and secondary outcomes, demonstrating moderate to large effects for both interventions, with cervical traction

DISCUSSION

This The findings of this study indicate that both daily and alternate-day prednisolone regimens effectively reduce disease activity in patients with rheumatoid arthritis (RA), as demonstrated by significant declines in DAS-28 scores over six weeks. No statistically significant differences were observed between the two treatment groups, suggesting that alternate-day dosing is a viable alternative to daily corticosteroid therapy. These results align with previous studies indicating that low-dose corticosteroids provide substantial symptomatic relief and disease control in RA while minimizing long-term structural joint damage (1). The non-inferiority of alternate-day dosing supports the hypothesis that intermittent corticosteroid administration may maintain anti-inflammatory efficacy while potentially reducing cumulative side effects, a concept that has been explored in other inflammatory conditions, including systemic lupus erythematosus and polymyalgia rheumatica (2).

While daily corticosteroids have been the standard practice in RA management, concerns about long-term complications have prompted investigations into alternative dosing schedules. The slightly lower incidence of metabolic side effects in the alternate-day group, particularly weight gain and hyperglycemia, is consistent with previous pharmacokinetic studies suggesting that alternate-day regimens allow for greater hypothalamic-pituitary-adrenal (HPA) axis recovery, thereby mitigating adrenal suppression and metabolic dysregulation (3). Furthermore, the absence of significant differences in inflammatory markers such as ESR and CRP between the groups reinforces the notion that the therapeutic efficacy of corticosteroids may not be strictly dependent on continuous daily exposure (4). These findings are in contrast with some earlier reports suggesting that alternate-day corticosteroids may lead to fluctuations in disease control, particularly in conditions with rapid inflammatory turnover (5). However, the present study suggests that in the context of RA, alternate-day dosing provides stable disease suppression over a short-term period, although longer studies are needed to confirm sustained benefits.

The comparable proportion of patients achieving DAS-28 remission in both groups highlights that disease control is not compromised by reducing corticosteroid frequency. Previous trials have demonstrated that low-dose corticosteroids, when used as adjuncts to DMARDs, improve clinical outcomes and delay radiographic progression in RA (6). The findings of this study extend this evidence by suggesting that an alternate-day regimen may offer similar benefits while potentially reducing corticosteroid burden. However, the clinical implications must be interpreted cautiously, given that alternate-day dosing may not be suitable for all patients, particularly those with severe, rapidly progressive disease requiring continuous anti-inflammatory effects (7). Another critical factor influencing corticosteroid response is patient adherence, which was not significantly different between groups in this study but has been reported in some literature as a challenge for alternate-day regimens due to perceived fluctuations in symptom relief (8). Future trials with patient-reported adherence assessments and long-term follow-up could provide further insight into this issue.

Despite its strengths, including the randomized design and blinded outcome assessment, this study has limitations that warrant consideration. The six-week follow-up period limits the ability to evaluate long-term efficacy, safety, and structural joint outcomes, which are essential for understanding the true clinical utility of alternate-day corticosteroid therapy. Additionally, while inflammatory markers and DAS-28 scores provide robust measures of disease activity, the study did not assess radiographic progression, which is crucial for determining long-term treatment effects (9). The sample size, although adequate for short-term efficacy assessment, may not be sufficiently powered to detect small but clinically meaningful differences in adverse events, particularly rare complications such as osteoporosis or cardiovascular risk associated with chronic corticosteroid use (10). Furthermore, the study population consisted of patients from a single center, potentially limiting generalizability to broader RA populations with varying disease phenotypes, comorbidities, and treatment histories.

Future research should focus on extended-duration trials to assess long-term outcomes, including corticosteroid-related morbidity and radiographic disease progression. Additionally, mechanistic studies investigating the differential effects of daily versus alternate-day corticosteroids on immune cell regulation and cytokine suppression in RA could provide valuable insights into optimizing dosing strategies. Given the emerging interest in personalized medicine, stratification of patients based on inflammatory burden, corticosteroid sensitivity, and genetic

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markers may help identify subgroups that benefit most from alternate-day regimens. Integrating these findings with real-world clinical data could further refine treatment guidelines and enhance individualized RA management strategies (11).

CONCLUSION

This study demonstrates that both daily and alternate-day prednisolone regimens effectively reduce disease activity in patients with rheumatoid arthritis, with no significant differences in DAS-28 scores or inflammatory markers after six weeks. The findings suggest that alternate-day prednisolone may serve as a viable alternative to daily corticosteroid therapy, potentially reducing metabolic adverse effects while maintaining therapeutic efficacy. These results have important clinical implications, as optimizing corticosteroid dosing strategies can enhance long-term treatment safety without compromising disease control. While the short-term efficacy of alternate-day regimens appears comparable to daily dosing, further long-term studies are needed to assess their impact on radiographic progression, patient adherence, and overall corticosteroid-related morbidity. Future research should explore individualized corticosteroid strategies based on patient-specific disease severity and risk factors to refine treatment guidelines and improve long-term RA management.

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