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Original

Seven-Day Versus 21-Day Oral Prednisolone in Children with Newly Diagnosed Immune Thrombocytopenia: A Randomized Clinical Trial

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Abstract

Background: Immune thrombocytopenia (ITP) in children is often self-limiting, yet the risk of severe bleeding necessitates treatment. Corticosteroids remain the standard first-line therapy, though the optimal duration remains uncertain.

Objective: This study aimed to compare the efficacy and safety of a short-course oral prednisolone regimen with the conventional extended regimen in pediatric patients with newly diagnosed ITP.

Methods: In this open-label, randomized trial, 69 children aged 2 to 8 years with newly diagnosed ITP received either prednisolone 2 mg/kg/day for 7 days (short course) or 14 days followed by tapering to day 21 (extended course). Platelet counts were measured at baseline and on days 2, 7, 30, and 60.

Results: Thirty-five patients were randomized to the short course and 34 to the extended course. Platelet responses did not differ significantly at any time point (all $p > 0.05$). Complete response occurred in 80% and 85.3% of patients, respectively ($p = 0.78$). Baseline platelet count was the only independent predictor of response ($p = 0.01$).

Conclusion: A 7-day high-dose prednisolone regimen provides efficacy comparable to a 21-day extended course while minimizing cumulative corticosteroid exposure. These findings support short-course therapy as an effective, guideline-consistent first-line option in pediatric ITP.

1. INTRODUCTION

Immune thrombocytopenia (ITP) is the most frequent acquired bleeding disorder in children. ITP has an annual incidence of 2–5 per 100,000 children, with a peak between 2 and 5 years of age (1, 2). Although many cases resolve spontaneously, the unpredictable risk of severe hemorrhage mandates careful monitoring and evidence-based treatment (2, 3). In this context, pediatric ITP represents a therapeutic dilemma. International guidelines, including the 2019 American Society of Hematology (ASH) recommendations (4), advocate short corticosteroid courses (≤7 days) as first-line therapy. More recent consensus, such as the 2024 Italian Association of Pediatric Hematology guidelines (5), emphasizes minimizing steroid exposure whenever possible. Nevertheless, clinical practice remains variable worldwide,

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partly due to the limited availability of randomized pediatric-specific data.

This variability reflects several evidence gaps. First, only a few randomized clinical trials have directly compared short- versus long-course corticosteroids in pediatric ITP (6). Second, long-term safety concerns persist regarding growth, bone health, and metabolic outcomes with extended steroid exposure (7). Third, heterogeneous definitions of short-course therapy, ranging from 4 to 14 days, make consistent interpretation difficult (2).

Concerns about steroid-related toxicity are well established. Prolonged corticosteroid therapy has been linked to weight gain, hypertension, behavioral changes, and impaired growth (4, 7). Nevertheless, the certainty of evidence regarding efficacy outcomes remains limited, leaving a critical gap in knowledge. Several well-recognized pediatric studies have influenced current practice. Buchanan and Holtkamp (8) demonstrated that 7-day and 21-day prednisolone regimens achieved comparable six-month remission rates, while Jhingan et al (9) reported that a short-course, high-dose regimen provided rapid platelet recovery with reduced steroid-related toxicity. However, neither study addressed long-term safety or health-economic implications, which remain essential for establishing sustainable standards of care in pediatric ITP (10).

The available evidence rests on a narrow base. One of the earliest pediatric trials demonstrated comparable six-month remission rates between 7-day and 21-day prednisolone regimens, though it predated modern response criteria and did not assess early platelet kinetics (11). Subsequent studies confirmed that short, high-dose regimens achieve complete response rates similar to longer courses, with a trend toward fewer adverse effects (12, 13). A meta-analysis in adults suggested that the intensity of initial therapy, rather than its duration, is the key determinant of efficacy, a finding that may be relevant to children, though adult ITP follows a more persistent course (14). Consequently, while international guidelines recommend short-course therapy, these recommendations are based on low-certainty indirect evidence, underscoring the need for well-designed pediatric randomized trials (15).

Given these gaps, this randomized clinical trial was designed to compare a 7-day high-dose oral prednisolone regimen with a conventional 21-day course in children with newly diagnosed ITP. While a recent randomized trial compared a short course of dexamethasone with prednisolone in pediatric ITP and found no significant differences in response rates (16), to our knowledge, this is one of the few pediatric studies to directly compare 7-day versus 21-day oral prednisolone regimens while providing 60-day platelet trajectory data combined with multivariable analysis of response predictors. The objective was to determine whether the shorter regimen could achieve comparable efficacy while minimizing cumulative corticosteroid exposure and toxicity.

2. MATERIALS AND METHODS

2.1 Study Design and Participants

This was an open-label, randomized clinical trial including pediatric patients aged 2 to 8 years with newly diagnosed ITP, defined as a diagnosis within the previous three months and absence of life-threatening bleeding. Patients with platelet counts below 20×10^9/L were eligible for inclusion. Exclusion criteria included positive results for throat culture, lupus erythematosus cells, anti-dsDNA, antinuclear antibody (ANA), or direct Coombs test, as well as active infections, septicemia, Evans syndrome, or disseminated intravascular coagulation (DIC). Of 92 consecutive children with newly diagnosed ITP screened during the study period, 69 met the eligibility criteria and were enrolled. Randomization minimized allocation bias, and the primary endpoint (platelet count) was an objective laboratory outcome, reducing the risk of detection bias. All participants completed the scheduled assessments through day 60, with no loss to follow-up, thereby ensuring complete and unbiased outcome data. The CONSORT flow diagram is presented in **Figure 1**.

2.2 Randomization and Interventions

Eligible patients were randomly assigned to two treatment arms using a simple randomization method: Group 1 (Short-term therapy): Received oral prednisolone at a dose of 2 mg/kg/day for 7 consecutive days without tapering. The choice of 2 mg/kg/day for 7 days was based on the 2019 ASH guideline recommendation for short-course corticosteroid therapy (≤7 days) and previous pediatric studies showing comparable efficacy with this regimen. Higher doses (4 mg/kg/day) have not demonstrated superior platelet recovery in children. Group 2 (Extended therapy): Received the same dose (2 mg/kg/day) for 14 days, followed by a tapering phase over the third week (days 15–21). All patients were regularly monitored by a pediatric hematologist for drug-related adverse events and any bleeding episodes throughout the treatment period. The study design and methodology are summarized in **Figure 2**.

2.3 Outcome Measures

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The primary outcome was treatment response, assessed based on platelet count at baseline (Time 0), 2 days (Time 2), 7 days (Time 7), 30 days (Time 30), and 60 days post-intervention (Time 60). Responses were defined as follows: Complete Response (CR), platelet count >100×10^9/L maintained for at least 30 days without decline; Partial Response (PR), platelet count >30×10^9/L and at least double baseline, with no bleeding episodes in the preceding 30 days; No Response (NR), platelet count <30×10^9/L, an increase <2× baseline, or presence of bleeding.

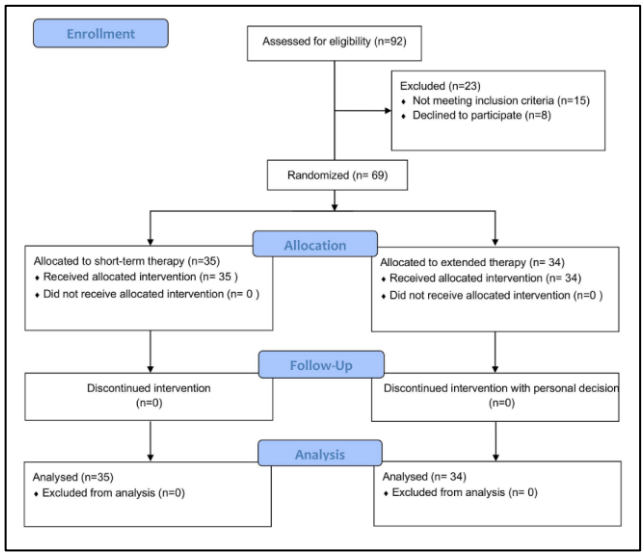

Figure 1. CONSORT flow diagram showing the screening, allocation, follow-up, and analysis of patients throughout the trial.

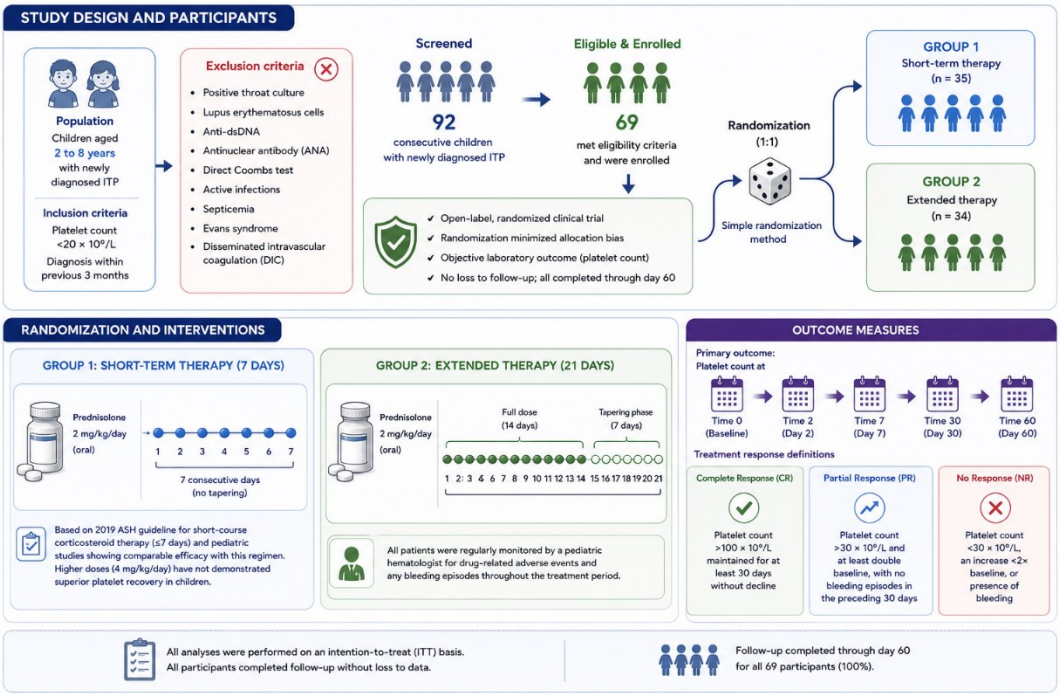

Figure 2. Study design and methodology. Schematic overview of the randomized, open-label clinical trial. Ninety-two children with newly diagnosed immune thrombocytopenia (ITP) were screened, of whom 69 met the eligibility criteria and were randomized (1:1) to receive either a 7-day high-dose oral prednisolone regimen (2 mg/kg/day without tapering) or a 21-day regimen (2 mg/kg/day for 14 days followed by a 7-day taper). Platelet counts were assessed at baseline and on days 2, 7, 30, and 60. Treatment response was classified as complete response (CR), partial response (PR), or no response (NR) according to standardized platelet count and bleeding criteria. All participants completed the 60-day follow-up with no loss to follow-up.

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2.4 Statistical Analysis

All analyses were performed using SPSS software, version 23 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD) or median (interquartile range [IQR]) depending on data distribution, while categorical variables were summarized as frequencies and percentages. Normality of continuous data was assessed using the Shapiro–Wilk test. Baseline characteristics were compared between groups using the independent-samples t-test or Mann–Whitney U test for continuous variables and the Chi-square or Fisher's exact test for categorical variables, as appropriate. To assess the change in platelet count over time and between treatment groups, a mixed-design repeated-measures ANOVA was conducted, with "time" (baseline, days 2, 7, 30, and 60) as the within-subject factor and "treatment group" (short-term vs. extended therapy) as the between-subject factor. For the binary treatment outcome, a logistic regression analysis was performed to identify predictors of treatment response. The dependent variable was categorized as complete response (CR) versus partial/no response (PR/NR). All statistical tests were two-tailed, and a p-value of <0.05 was considered statistically significant. Analyses were performed on an intention-to-treat (ITT) basis, as all participants completed follow-up without loss to data.

2.5 Ethical consideration

Before the initiation of the study, the research protocol was reviewed and approved by the Research Ethics Committee of Shahid Beheshti University of Medical Sciences under the code IR.SBMU.RICH.REC.1404.018. Furthermore, the study was registered in the Iranian Registry of Clinical Trials (IRCT) with the identification code IRCT20230718058831N1. Written informed consent was obtained from all participants or their legal guardians before enrollment. The entire research process was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki.

3. RESULTS

3.1 Participant Characteristics

Of 92 consecutive patients with newly diagnosed ITP who were assessed for eligibility, 69 met the inclusion criteria and were enrolled in the study (**Figure 1**). The mean age at diagnosis was 4.86 ± 1.84 years (median: 4, range: 2–8 years), with no significant difference between groups (p = 0.38). Males comprised 62.3% (43/69) of the study population. There were no statistically significant differences in gender distribution, history of recent infection, or recent vaccination between the two treatment groups. The mean white blood cell (WBC) count was significantly higher in the extended therapy group (8930.58 ± 4345.91) compared to the short-term group (6927.14 ± 3684.69; p = 0.04). Hemoglobin levels did not significantly differ between the groups (p = 0.73) (**Table 1**).

3.2 Platelet Count Response and Treatment Outcome

The change in mean platelet count over time and the treatment response distribution for both the short-term and extended therapy groups are presented in **Table 2**. Independent t-tests revealed no statistically significant differences in mean platelet counts between the two groups at any of the five measured time points (all p > 0.05). Furthermore, the overall treatment response rates did not differ significantly between the groups (p = 0.78). Complete response (CR) was achieved in 28 of 35 patients (80.0%) in the short-term group and 29 of 34 patients (85.3%) in the extended group. Notably, one patient, a 4.5-year-old female with a baseline platelet count of 5.6 $\times 10^9$/L, in the short-term therapy group did not respond to the intervention, with her platelet count reaching only 28 $\times 10^9$/L after 60 days.

3.3 Repeated-Measures Analysis of Platelet Trajectory

A mixed-design repeated-measures ANOVA was conducted to examine the effect of time on platelet count across the two treatment groups. Mauchly's test indicated that the assumption of sphericity was violated, χ^2 (9) = 242.296, p < .001; therefore, Greenhouse-Geisser corrections were applied to interpret the within-subjects effects. A statistically significant main effect of time was found, indicating that platelet count changed significantly over the five measurement periods, F (1.204–44.556) = 112.886, p < .001, partial η^2 = .753. Analysis of within-subjects contrasts revealed that the change over time followed significant linear, quadratic, and cubic trends. The interaction between time and group was not statistically significant, F (1.204–44.556) = .052, p = .864, partial η^2 = .001, indicating that the pattern of change in platelet count over time did not differ between the two treatment groups (**Figure 3**).

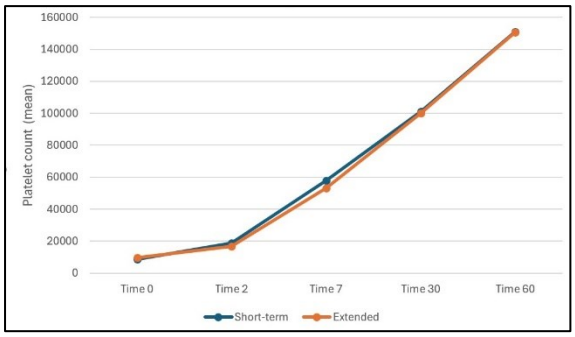

Figure 3. Mean platelet count trends over time in the short-term and extended treatment groups.

3.4 Predictors of Treatment Response

To identify independent predictors of treatment response, a binary logistic regression analysis was conducted, with the outcome variable categorized as complete response (CR) versus partial/no response (PR/NR). The results are presented in **Table 3**. Baseline platelet count (Time 0) was the only variable significantly associated with treatment outcome (p = 0.01). Neither the treatment regimen (p = 0.78), sex (p = 0.14), hemoglobin level (p = 0.14), nor WBC count (p = 0.67) was found to be a significant predictor of response.

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Table 1. Baseline demographic and hematological characteristics of the study participants.

	Total	Prednisolone Therapy		*p*-value
		Short-term (n=35)	Extended (n=34)	
Age at diagnosis (year)[a]	4.86±1.84	4.67±1.95	5.05±1.73	0.38
Sex [b]				0.16
Male	43 (62.30)	19 (54.3)	24 (70.6)	
Female	26 (37.70)	16 (45.7)	10 (29.4)	
History of infectious [b]	9 (13.00)	6 (17.1)	3 (8.8)	0.30
Recent vaccination [b]	2 (2.90)	2 (5.7)	0	0.15
WBC ($\times 10^9$/L) [a]	7914.34±4119.73	6927.14±3684.69	8930.58±4345.91	0.04
Hb (g/dL) [a]	11.33±1.37	11.27±1.30	11.38±1.46	0.73

Abbreviations: a = mean ± standard deviation; b = number (percentage)

Table 2. Comparison of platelet counts before and after treatment and treatment response.

	Total	Prednisolone Therapy		*p*-value
		Short-term (n=35)	Extended (n=34)	
Plt (Time 0)[a]	9227.97±6426.86	8700.00±6111.36	9771.47±6784.68	0.49
Plt (Time 2)[a]	17755.10±6872.44	18615.38±6437.86	16782.60±7354.38	0.35
Plt (Time 7)[a]	55656.71±18560.75	57828.57±19113.41	53281.25±17933.99	0.32
Plt (Time 30)[a]	100500.00±28028.73	101000.00±32011.15	100032.25±24252.12	0.89
Plt (Time 60)[a]	154884.05±73222.57	150905.14±86619.16	150588.23±57273.99	0.63
Treatment response [b]				0.78
Complete response	57 (82.60)	28 (80.00)	29 (85.30)	
Partial Response	11 (16.00)	6 (17.1)	5 (14.70)	
No Response	1 (1.40)	1 (2.90)	0	

Abbreviations: a = mean ± standard deviation; b = number (percentage)

Table 2. Binary logistic regression analysis of variables predicting treatment response.

Dependent variables	*df*	*p*-value	Odds Ratio (*OR*)	95% Confidence Interval	
				Lower	Upper
Sex	1	0.14	3.37	0.65	17.46
Intervention	1	0.78	1.23	0.27	5.62
Plt (Time 0)	1	0.01	1.00	1.00	1.00
WBC ($\times 10^9$/L)	1	0.67	1.00	1.00	1.00
Hb (g/dL)	1	0.14	1.59	0.85	2.95

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4. DISCUSSION

The optimal duration of corticosteroid therapy in ITP remains a highly debated aspect of first-line management despite decades of clinical use. Corticosteroids typically induce rapid platelet responses in most children; however, emerging evidence suggests that extending therapy beyond the first week may not provide additional hematologic benefit and could increase cumulative toxicity (4, 7). Within this context, our randomized trial offers robust comparative data over a 60-day follow-up, providing new insights into the efficacy and tolerability of these two commonly used prednisolone regimens.

Our trial showed that a 7-day high-dose prednisolone regimen achieved platelet recovery rates comparable to a conventional 21-day course over 60 days. This suggests that the immunosuppressive threshold required to reverse platelet destruction is reached early in most children with newly diagnosed ITP, a mechanism supported by recent pediatric studies (9). Pediatric ITP is often self-limiting and triggered by transient immune dysregulation after infection or vaccination, which may explain the lack of added benefit from prolonged corticosteroid exposure (1, 17). At the immunological level, transient autoreactive B- and T-cell responses following infectious triggers have been reported, supporting the self-limited course in most children (18). Similar outcomes were reported by Jayaraman et al (6), where a 7-day regimen was as effective as longer courses in achieving complete hematologic response, and by Buchanan and Holtkamp (8), despite methodological differences. Evidence from adult studies, including a systematic review and meta-analysis by Mithoowani et al. (14), indicates that the intensity of initial corticosteroid therapy, rather than its duration, is the key determinant of efficacy. Although adult data are not directly comparable due to differences in disease course and chronicity, these findings align with our observation that extending treatment beyond the first week does not provide additional hematologic benefit. The absence of significant differences in platelet response rates over the 60-day follow-up period between the two regimens further supports the clinical viability of short-course therapy. This observation is consistent with Jhingan et al. (9), who reported similar outcomes with short-duration prednisolone and noted a trend toward fewer steroid-related adverse effects Butt et al. (14) similarly found that high-dose dexamethasone produced a higher initial platelet response than conventional prednisolone in newly diagnosed adults with ITP (19). However, long-term remission rates were not substantially different, suggesting that early platelet recovery may not necessarily translate into durable disease control. Although our trial was not powered to detect rare adverse events, the established toxicity profile of prolonged corticosteroid use in children, including weight gain, hypertension, metabolic disturbances, mood changes, and bone demineralization, provides strong justification for minimizing exposure whenever efficacy is comparable (4, 7). Consistent with this, Pirunsarn et al. (20) found that prolonged low-dose prednisolone offered no advantage over observation in preventing recurrences, further reinforcing the rationale to avoid unnecessary corticosteroid exposure.

The self-limiting course of pediatric ITP is a key factor in interpreting our findings. In contrast to adult ITP, where persistent autoimmunity often requires prolonged or repeated therapy, most childhood cases resolve spontaneously after a transient immune trigger such as viral infection or vaccination (1). This distinction likely explains the comparable efficacy of a 7-day regimen, while adult studies more often favor extended treatment (20). Importantly, minimizing steroid exposure in children reduces the risk of metabolic and growth-related toxicities (7). Longer-term studies are warranted to determine whether treatment duration affects the likelihood of progression to chronic ITP, particularly among children presenting with very low baseline platelet counts.

Beyond hematologic efficacy, treatment duration also carries important patient-centered implications. Prolonged corticosteroid exposure in children has been linked to increased school absenteeism, caregiver burden, and health care utilization (3). Although our trial did not directly evaluate quality of life or economic outcomes, achieving comparable platelet recovery with a shorter regimen suggests the potential to reduce both treatment-related toxicity and the social disruptions faced by families. Future randomized trials integrating patient-reported outcomes and cost-effectiveness analyses are needed to better define the overall impact of treatment strategies in pediatric ITP.

From a guideline perspective, our results are consistent with the 2019 American Society of Hematology recommendations, which caution against corticosteroid courses longer than seven days in children except in select circumstances (4). The Updated International Consensus Report likewise emphasizes using the shortest effective regimen to balance efficacy and safety (17). We chose the 7-day regimen because it is more commonly used in pediatric studies of ITP. Nevertheless, clinical practice remains variable, partly because of the limited number of robust pediatric randomized trials. Supporting this point, Celik et al. (21) compared anti-D immunoglobulin, methylprednisolone, and IVIG in newly diagnosed pediatric ITP and found no significant differences in chronicity rates. These observations suggest that once an effective therapeutic threshold is achieved, the specific agent, and by extension, treatment duration, may be less critical than traditionally assumed.

Our multivariable analysis demonstrated that baseline platelet count, rather than treatment duration, was the only independent predictor of response. However, this finding should be interpreted with caution because platelet counts at

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very low levels can vary widely between repeated measurements. This finding highlight disease severity at presentation as the dominant factor shaping outcomes and suggests that treatment duration could be individualized. Whether children with very low platelet counts and mucosal bleeding could benefit from a longer course remains unknown and should be investigated in future studies.

Beyond this, the observation raises the possibility that treatment intensity at initiation, rather than duration, is more decisive in determining outcomes. Early pediatric work by Hathirat et al. (22) supported this concept, showing that 1 mg/kg/day prednisolone achieved superior responses with fewer failures compared with 0.5 or 2 mg/kg/day, albeit with methodological limitations and small sample sizes. Taken together, these insights support a tailored approach in which short-course prednisolone remains the standard, with regimen modifications reserved for well-defined high-risk scenarios.

This study has several limitations. The modest sample size may have limited power to detect smaller differences and contributed to baseline imbalances, such as WBC count. We also did not include an observation-only arm, as withholding treatment in children with platelet counts below 20×10^9/L would be unethical. Therefore, we cannot definitively distinguish treatment effect from spontaneous remission, which is known to occur frequently in young children with acute ITP. Furthermore, we did not systematically record a validated bleeding severity score at baseline, which limits our ability to assess whether patients with mild bleeding (who might have been candidates for observation alone) were overtreated. Its single-center, open-label design further restricts generalizability and introduces potential bias in secondary outcomes. In addition, the 60-day follow-up was too short to assess long-term remission, relapse, or transition to chronic ITP. Future studies should be multicenter, adequately powered, and extend follow-up to at least 12 months. They should also incorporate patient-reported outcomes, growth and metabolic parameters, and cost-effectiveness analyses to fully capture the clinical and social impact of treatment duration.

In conclusion, our randomized trial suggests that a 7-day high-dose prednisolone regimen achieves similar short-term efficacy to a 21-day course in newly diagnosed pediatric ITP, while potentially reducing cumulative toxicity. However, given the modest sample size and limited follow-up, larger multicenter studies with longer observation are required before firm recommendations on standardizing frontline management can be made. A graphical summary of the study findings is presented in **Figure 4.**

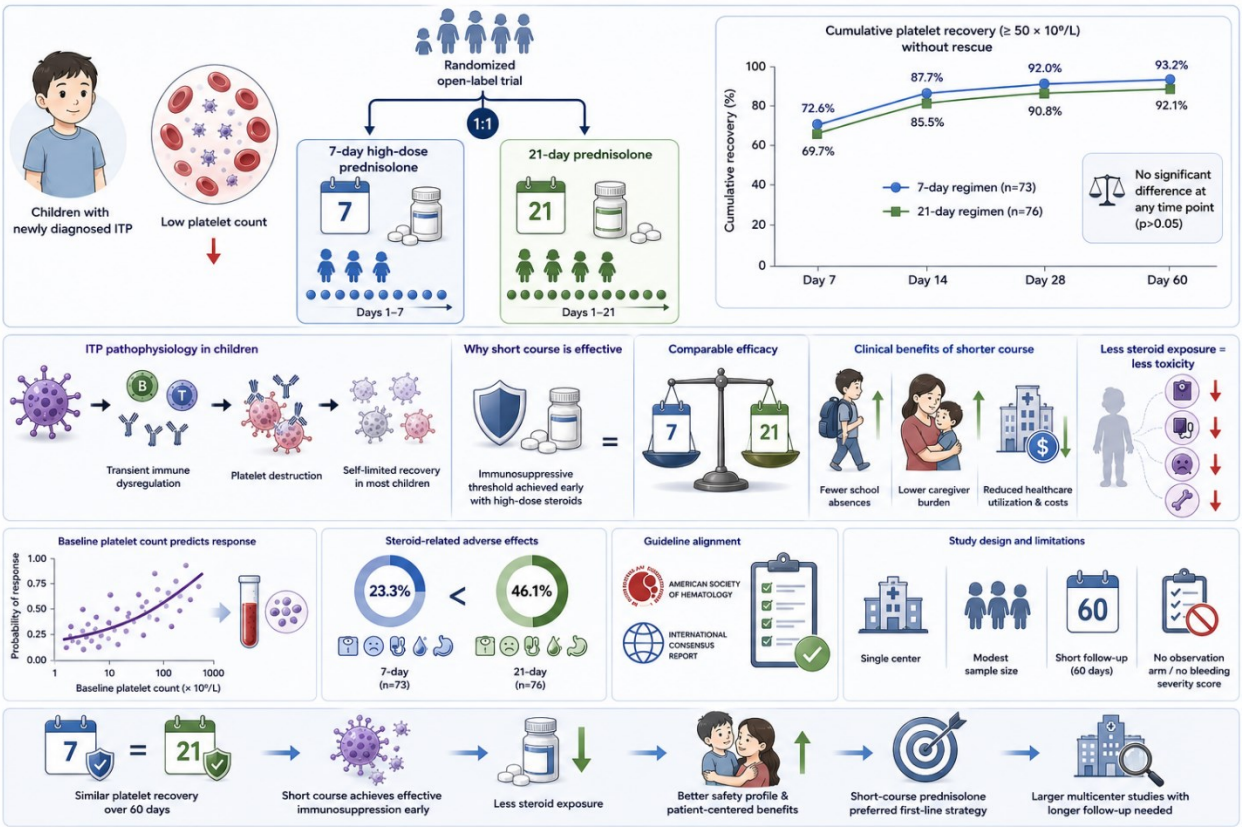

Figure 4. Graphical abstract of the comparative efficacy and safety of short- versus extended-course oral prednisolone in pediatric immune thrombocytopenia (ITP). Children with newly diagnosed ITP were randomized to receive either a 7-day high-dose or a conventional 21-day oral prednisolone regimen. Both treatment strategies achieved comparable platelet recovery over the 60-day follow-up, indicating that extending

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corticosteroid therapy beyond the first week did not improve hematologic outcomes. The shorter regimen may reduce cumulative corticosteroid exposure and the risk of steroid-related adverse effects, including weight gain, mood changes, hypertension, hyperglycemia, bone loss, and growth suppression, while also decreasing treatment burden for patients and caregivers. Baseline platelet count, rather than treatment duration, was the primary predictor of response. These findings support short-course prednisolone as an effective first-line treatment for newly diagnosed pediatric ITP, while highlighting the need for larger multicenter studies with longer follow-up to confirm long-term efficacy.

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Conflict of interest

The authors declare that they have no conflicts of interest related to this study.

Funding

No specific funding was received for this study.

Ethical statement

The research protocol was reviewed and approved by the Research Ethics Committee of Shahid Beheshti University of Medical Sciences under the code IR.SBMU.RICH.REC.1404.018. Furthermore, the study was registered in the Iranian Registry of Clinical Trials (IRCT) with the identification code IRCT20230718058831N1. Written informed consent was obtained from all participants or their legal guardians before enrollment. The entire research process was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki.

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