

Efektivitas Pemberian Vitamin E dalam Mencegah Kejadian Neuropati Vinkristin pada Anak dengan Leukemia Limfoblastik Akut: Hasil Ad Interim Uji Klinis Acak Terkontrol = Effectiveness of Vitamin E Administration in Preventing Vincristine-Induced Neuropathy in Children with Acute Lymphoblastic Leukemia: An Interim Result of Randomized Controlled Clinical Trial

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Abstrak

Latar Belakang: Prevalensi neuropati perifer setelah terapi vinkristin dilaporkan cukup tinggi. Beberapa penelitian menunjukkan manfaat vitamin E dalam mencegah neuropati perifer akibat agen kemoterapi, termasuk vinkristin, tetapi hingga saat ini belum ada studi yang meneliti efek tersebut pada pasien anak. Penelitian ini bertujuan untuk mengkaji peran vitamin E dalam pencegahan neuropati perifer akibat kemoterapi vinkristin pada anak dengan leukemia limfoblastik akut. Tujuan: Untuk mengetahui efektivitas vitamin E dalam mencegah neuropati pada anak dengan LLA yang mendapat terapi vinkristin. Metode: Studi uji klinis acak terkontrol di Rumah Sakit Dr. Cipto Mangunkusumo menggunakan subjek pasien anak usia 0-18 tahun yang terdiagnosis LLA pada bulan Januari 2025 hingga Mei 2025. Randomisasi tersamar ganda dilakukan untuk membagi ke dalam 2 kelompok yang mendapat terapi vitamin E dan plasebo. Subjek dilakukan pemeriksaan kecepatan hantar saraf (KHS) sebelum dan sesudah intervensi. Faktor yang dinilai meliputi penurunan fungsi saraf berdasarkan gejala dan pemeriksaan KHS. Hasil: Subyek penelitian sebanyak 13 pasien dengan rerata usia sampel 6,76 tahun, mayoritas subyek lelaki sebanyak 10 pasien (76,9%). Sebanyak 5 subjek penelitian (69,2 %) pasien memiliki status nutrisi gizi baik dan 4 subjek (30,8%) gizi kurang. Sebanyak satu (7,7%) subjek terklasifikasi LLA risiko standar dan 12 (92,3%) risiko tinggi. Sebanyak 7 (53,8%) subjek menjalani kemoterapi fase induksi 1A protokol LLA tahun 2024 dan 6 (46,2%) subjek lainnya menjalani kemoterapi fase reinduksi 2A protokol LLA 2024. Median dosis riil vinkristin adalah 4,05 mg dengan rerata dosis kumulatif 5,31 mg/m². Sebanyak 10 subjek mendapat vitamin E dan 3 subjek mendapat plasebo. Terdapat 2 dari 10 (20%) subjek yang mendapat vitamin E mengalami neuropati pada pemeriksaan KHS. Tidak ada subjek yang mendapat plasebo yang mengalami neuropati ($p=0,577$). Analisis ad interim menunjukkan risiko relatif mengalami neuropati vinkristin adalah 0,8 (IK 95% 0,90 – 1,74), namun hal ini disebabkan besar sampel yang kurang. Simpulan: Efektivitas vitamin E belum dapat disimpulkan dalam mencegah neuropati perifer pada anak dengan leukemia limfoblastik akut yang mendapat terapi vinkristin. Studi ini perlu diteruskan sampai mencapai besar sampel yang dibutuhkan untuk menarik kesimpulan akhir/definitif.

.....Background: The prevalence of vincristine-induced peripheral neuropathy has been reported to be quite high. Several studies have demonstrated the benefits of vitamin E in preventing chemotherapy-induced peripheral neuropathy, including that caused by vincristine. However, to date, no studies have investigated this effect specifically in pediatric patients. This study aims to evaluate the role of vitamin E in the prevention of vincristine-induced peripheral neuropathy in children with acute lymphoblastic leukemia. Objective: To determine the effectiveness of vitamin E in preventing neuropathy in children with acute lymphoblastic leukemia (ALL) undergoing vincristine therapy. Methods: A randomized controlled clinical

trial was conducted at Dr. Cipto Mangunkusumo Hospital involving pediatric patients aged 0–18 years diagnosed with ALL from January 2025 to May 2025. Double-blind randomization was performed to divide subjects into two groups receiving either vitamin E or placebo. Nerve conduction velocity (NCV) tests were conducted before and after the intervention. Evaluated factors included nerve function decline based on symptoms and NCV examination. Results: The study included 13 patients with a mean age of 6.76 years; the majority were male (10 patients, 76.9%). Most subjects (69.2%) had good nutritional status, while 30.8% were malnourished. One subject (7.7%) was classified as standard-risk ALL and 12 (92.3%) as high-risk. Seven (53.8%) subjects underwent induction phase 1A chemotherapy per the 2024 ALL protocol, and six (46.2%) underwent reinduction phase 2A chemotherapy. The median actual vincristine dose was 4.05 mg, with a mean cumulative dose of 5.31 mg/m². Ten subjects received vitamin E and three received placebo. Among those receiving vitamin E, 2 out of 10 (20%) developed neuropathy on NCV testing, while 8 (80%) did not. No subjects in the placebo group developed neuropathy (p=0.577). The interim analysis showed that the relative risk of developing vincristine-induced neuropathy was 0.8 (95% CI: 0.90–1.74); however, this is due to the small sample size. Conclusion: Effectiveness of vitamin E in preventing peripheral neuropathy in children with acute lymphoblastic leukemia receiving vincristine therapy cannot be concluded due small sample size. This study needs to be continued until the required sample size is reached in order to draw a final or definitive conclusion.