

## Uji klinis tersamar acak ganda pemberian parasetamol selama pasca imunisasi DTwP-Hep B-Hib = Effect of prophylactic paracetamol administration at Time of DTwP-Hep B-Hib immunization: double blind, randomized clinical controlled trial

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### Abstrak

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Latar belakang: Demam, pengurangan waktu tidur, nyeri dan reaksi lokal adalah beberapa kejadian ikutan pasca imunisasi. Untuk mencegah hal tersebut baik tenaga medis maupun orang tua memberikan profilaksis parasetamol pasca imunisasi. Peraturan Menteri Kesehatan Republik Indonesia dan Pedoman Imunisasi IDAI belum menetapkan secara tegas boleh atau tidaknya pemberian profilaksis parasetamol pasca imunisasi.

Tujuan: Mengetahui efektivitas pemberian profilaksis parasetamol oral untuk mencegah kejadian ikutan pasca imunisasi kombinasi DTwP-Hep B-Hib.

Metode: Uji Klinis tersamar acak ganda (double blind randomized control trial) dengan pemberian parasetamol dan plasebo pada pasien pasca imunisasi kombinasi DTwP-Hep B-Hib di Puskesmas Kecamatan Kramat Jati dan Puskesmas Kelurahan Batu Ampar selama September 2015 sampai Oktober 2015. Satu hari pasca imunisasi, kelompok perlakuan diberikan parasetamol (40-50 mg/kgBB/hari), terbagi 4 dosis sedangkan kelompok kontrol, mendapatkan plasebo. Selama empat hari pasca imunisasi dilakukan pengukuran suhu aksila, lama tidur, dan reaksi inflamasi lokal.

Hasil: Subjek penelitian ini terdiri dari 100 bayi yang mendapatkan imunisasi kombinasi DTwP-Hep B-Hib ketiga. Karakteristik dasar meliputi usia, jenis kelamin, dan status gizi tidak berbeda di kedua kelompok. Subjek penelitian mendapatkan profilaksis parasetamol (50 subjek) dan profilaksis plasebo (50 subjek). Seluruh subjek penelitian tidak demam, tidak mengalami gangguan tidur, dan tidak ditemukan reaksi lokal. Pemberian parasetamol 24 jam pasca imunisasi DTwP-Hep B-Hib menunjukkan penurunan suhu 0,1 OC - 0,2 OC yang bermakna secara statistik ( $p < 0,05$ ) pada 24 jam pertama pasca imunisasi. Pemberian parasetamol menunjukkan waktu tidur yang lebih lama namun tidak bermakna secara statistik ( $p > 0,05$ ) pada lama tidur.

**ABSTRACT**  
Background: Fever, decreased sleep time, pain and local reaction are adverse event following vaccination especially DTwP vaccine. Parent and also medical staff almost give paracetamol prophylactic to reduce adverse event after vaccination. Peraturan Menteri Kesehatan Republik Indonesia (Ministry of Health Republic of Indonesia Health Law) and Pedoman Imunisasi IDAI (Indonesia Pediatric Society Immunization Guideline) never explicitly allowed or not prophylactic administration of paracetamol post immunization.

Objective: To assess the efficacy of prophylactic administration of paracetamol compared with placebo for prevent adverse event after immunization.

Method: A randomized double-blind clinical trials by administer paracetamol and placebo in patients post-immunization DTwP - Hep B - Hib in Kramat Jati district primary health care and Batu Ampar sub-district primary health care during September 2015 to October 2015. One day after vaccination, the treatment group was given paracetamol (40-50 mg/kg/day), divided into 4 doses, while the control group was given placebo. Axillary temperature, time of sleep, and local reactions was evaluated until 4 day after vaccination.

Result: Subjects of this study consisted of 100 infants (50 with paracetamol & 50 with placebo) after DTwP-Hep B-Hib third primary immunization. The baseline characteristic including age, gender, and nutritional status were similar in both groups. All subject showed no fever, no local reaction, and no sleep disturbance. Prophylactic paracetamol 24 hours post DTwP-Hep B-Hib immunization showed a decrease in temperature of 0.1 OC - 0.2 OC ( $p < 0.05$ ) in the first 24 hours postimmunization.

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