

## Evaluasi Profil Eritrosit, Kimia Darah, dan Tumor Marker (CA15-3 dan CEA) Setelah Paparan *Electro-Capacitive Cancer Therapy* pada Sukarelawan Sehat (Uji Klinis Tahap 1)

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### INTISARI

Kanker payudara merupakan salah satu penyebab kematian tertinggi di Indonesia yang menyerang pada wanita. Terapi penyakit kanker di dunia medis umumnya terdiri dari 3 tindakan, yaitu operasi, radioterapi, dan kemoterapi. Penanganan medis tersebut memiliki efek samping dan biaya yang besar. ECCT merupakan metode terapi kanker berbasis medan listrik frekuensi menengah dan intensitas rendah yang didesain berbentuk rompi. Hasil uji praklinis menunjukkan bahwa alat terapi ECCT mampu menekan sel kanker dengan cara menghambat proliferasi pada saat sel kanker yang mengalami pembelahan. Tujuan dari penelitian ini adalah untuk menganalisa pengaruh terapi medan listrik statis ECCT frekuensi menengah (100kHz) intensitas rendah (18 Vvp) terhadap profil sel darah merah, kimia darah dan penanda tumor. Penelitian ini merupakan uji klinis tahap 1 yang melibatkan sukarelawan sehat yang dipilih sebagai subjek penelitian dan diseleksi secara ketat sebanyak 40 orang yang memenuhi kriteria inklusi dan eksklusi. Subjek yang lolos di bagi menjadi 2 kelompok perlakuan yaitu 20 orang menggunakan rompi ECCT dengan medan listrik (*ON*) dan 20 orang menggunakan rompi ECCT tanpa medan listrik (*OFF*). Penggunaan rompi ECCT dilakukan selama 21 hari dan digunakan selama 2×5 jam/hari. Pemeriksaan klinis total dilakukan sebanyak dua kali yaitu *pre* dan *post* terapi uji klinis. Parameter klinis yang digunakan pada penelitian ini adalah profil hematologis lengkap meliputi *Red Blood Cell Distribution Width* (RDW), *Red Blood Cell* (RBC), *Hemoglobin* (Hb), *Hematocrit* (HCT), *Mean Corpuscular Volume* (Mcv), *Mean Corpuscular Hemoglobin* (MCH), *Mean Corpuscular Hemoglobin Concentration* (MCHC), kimia darah (SGPT, SGOT, ureum, kreatinin, bilirubin), dan penanda tumor (CA 15-3 dan CEA). Data dianalisis secara statistik berdasarkan uji t-Test dan ANOVA. Hasil penelitian menunjukkan bahwa nilai rata-rata dan SD dari parameter uji kelompok ECCT secara umum tidak berbeda secara signifikan ( $p>0,05$ ) berdasarkan uji T dan hasil secara keseluruhan menunjukkan masih dalam kisaran normal (*reference value*) laboratorium RSA UGM. Kesimpulan dari penelitian ini yaitu paparan medan listrik statis frekuensi menengah (100 kHz) dan intensitas rendah (18 Vvp) dari alat ECCT yang berbentuk rompi dinyatakan aman berdasarkan parameter profil hematologi sel darah merah, kimia darah, dan penanda tumor CEA dan CA 15-3.

**Kata Kunci:** sukarelawan sehat, profil sel darah merah, kanker payudara, ECCT, tumor markers, kimia darah.

## Evaluation of Erythrocyte Profile, Blood Chemistry, and Tumor Markers (CA15-3 and CEA) After Exposure to Electro-Capacitive Cancer Therapy in Healthy Volunteers (Phase 1 Clinical Trial)

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### ABSTRACT

Breast cancer is one of the leading causes of death in Indonesia, affecting women. Cancer therapy in the medical world generally consists of 3 actions, namely surgery, radiotherapy, and chemotherapy. Medical treatment has side effects and large costs. ECCT is a cancer therapy method based on medium-frequency and low-intensity electric fields designed in the form of a vest. Preclinical test results show that the ECCT therapy device is able to suppress cancer cells by inhibiting proliferation when cancer cells are undergoing division. The aim of the study was to analyze the effect of low-intensity (100kHz) medium frequency (100kHz) static electric field therapy (18 Vvp) on red blood cell profiles, blood chemistry and tumor markers. This study is a phase 1 clinical trial involving healthy volunteers who were selected as research subjects and selected strictly as many as 40 people who met the inclusion and exclusion criteria. Subjects who passed were divided into 2 treatment groups, namely 20 people using an ECCT vest that was electrified (*ON*) and 20 people using an ECCT vest that was not electrified (*OFF*). The use of the ECCT vest was carried out for 21 days and used for  $2 \times 5$  hours / day. Total clinical examination was carried out twice, namely pre and post-therapy clinical trials. The clinical parameters used in this study were a complete hematological profile including Red Blood Cell Distribution Width (RDW), Red Blood Cell (RBC), Hemoglobin (Hb), Hematocrit (HCT), Mean Corpuscular Volume (Mcv), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), blood chemistry (SGPT, SGOT, urea, creatinine, bilirubin), and tumor markers (CA 15-3 and CEA). Data were analyzed statistically based on t-test and ANOVA. The results showed that the mean and SD values of the test parameters of the ECCT group in general were not significantly different ( $p > 0.05$ ) based on the T test. However, the RDW, MCH, and CEA tumor marker parameters experienced significant changes but the results were statistically significant. overall is still within the normal range (reference value) of the UGM RSA laboratory. The conclusion of this study is that exposure to a medium-frequency (100kHz) and low-intensity (18 Vvp) static electric field from a vest-shaped ECCT device was declared safe based on the parameters of the haematological profile of red blood cells, blood chemistry, and tumor markers CEA and CA 15-3.

**Keywords:** healthy volunteers, red blood cell profiles, breast cancer, ECCT, tumor markers, blood chemistry.