

Efek metformin dan DLBS3233 terhadap kadar anti-mullerian hormon pada wanita sindrom ovarium polikistik: uji klinis acak tersamar ganda = The effect of metformin and cinammon DLBS3233 on anti mullerian hormone in women with polycystic ovary syndrome a double blind randomized controlled trial

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Abstrak

**TUJUAN:** Mengetahui efek metformin atau DLBS3233 terhadap kadar AMH.

**LATAR BELAKANG:** SOPK merupakan sindrom yang diketahui berkaitan dengan resistensi insulin dalam patofisiologi dan peranan AMH dalam patogenesis. Maka salah satu bagian dari tatalaksana SOPK adalah dengan pemberian insulin sensitizing agent ISA. ISA yang telah banyak digunakan yaitu metformin yang terbukti dalam memperbaiki siklus haid, namun obat ini juga menimbulkan efek samping seperti keluhan gastrointestinal yang cukup berat. Sehingga perkembangan obat herbal seperti fraksi bioaktif DLBS3233 memberikan harapan akan ISA yang efektif, namun memiliki efek samping minimal. Peranan ISA dalam efek perubahan AMH masih kontroversial, dan hanya ditemui penelitian yang meneliti metformin.

**DESAIN DAN METODE:** Penelitian ini menggunakan desain uji klinis acak tersamar ganda yang berlangsung pada bulan Maret 2013 hingga Juni 2015 di klinik Yasmin, RSCM Kencana dan RS Hasan Sadikin, Bandung. Subjek penelitian akan mendapatkan metformin sebanyak 2x750mg atau DLBS3233 1x100mg per hari selama enam bulan. Evaluasi kadar AMH akan dilakukan sebanyak dua kali, sebelum dan sesudah pengobatan.

**HASIL:** Sebanyak 20 subjek mendapat metformin dan 18 subjek mendapat DLBS3233. Rerata kadar AMH sebelum pengobatan didapati 9,30 5,06 ng/mL dan 11,27 6,47 ng/mL. Pasca pengobatan, didapati penurunan kadar AMH yang signifikan sebesar 1,52 0,07 p < 0,001. Penurunan kadar AMH didapati lebih tinggi pada grup metformin bila dibandingkan dengan DLBS3233 ? AMH = 1,83 ng/mL vs 1,15 ng/mL. Namun, metformin menimbulkan efek samping yang lebih signifikan dibandingkan DLBS3233 p=0,01. Sebanyak 7 pasien 18,42 hamil selama penelitian ini. Namun efek samping pengobatan jauh dirasakan oleh subjek yang mendapatkan metformin dibandingkan DLBS3233 p=0,01.

**KESIMPULAN:** Baik metformin atau fraksi bioaktif DLBS3233 dapat menurunkan kadar AMH, dan DLBS3233 merupakan pilihan terapi SOPK dengan efek samping yang minimal.

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**OBJECTIVE:** To determine the effect of metformin and DLBS3233 on serum AMH level.

**BACKGROUND:** PCOS is known to be associated with insulin resistance in the pathophysiology and Anti Mullerian Hormone AMH in the pathogenesis. Thus, one of management of PCOS is to give insulin sensitizing agent ISA. Type of ISA which has been widely used is metformin which proven to improve menstrual cycle, but this medication cause major side effect such as gastrointestinal problems. So, the development of herbal medicine such as Bioactive Fraction DLBS3233, offer effective medicine, with minimal side effects. To date, the role of ISA to effects the changes in AMH still controversial, and studies only examine the effect of metformin to the level of AMH.

**METHOD:** Double blind randomized controlled trial was conducted in Yasmic Clinic, Cipto

Mangunkusumo General Hospital, Kencana and Hasan Sadikin hospital, Bandung within March 2013 until June 2015. PCOS patient diagnosed using Rotterdam All participant get daily dose of metformin 2x750mg or DLBS3233 1x100mg for six months. Evaluation of serum AMH level was conducted twice prior therapy and after the completion of the therapy. Protocol analysis was carried out upon differences of AMH using SPSS 20.

RESULTS: 20 subjects received metformin, while 18 subject received DLBS3233. Level of AMH prior medication was known to be 9,30 5,06 ng mL and 11,27 6,47 ng mL. After six months of therapy, there is significant decrease of AMH level of 1,52 0,07 p 0,001. The decrease level of AMH was observed higher in metformin group compared to DLBS3233 AMH 1,83 ng mL vs 1,15 ng mL. However, metformin causing more side effects compared to DLBS3233 p 0,01. There are total of 7 subjects 18,42 pregnant during the studies.

CONCLUSION: There rsquo s a significant decrease of AMH level after administration of either metformin or DLBS3233.