Sexual Function/Dysfunction: Medical, Hormonal & Non-surgical Therapy I

Moderated Poster 47

Sunday, May 5, 2024 **7:00 AM-9:00 AM**

MP47-01

PREPED STUDY: A RANDOMISED, DOUBLE-BLIND CONTROLLED TRIAL TO EVALUATE THE EFFICACY OF INTRACAVERNOSAL INFUSION OF PLATELET RICH PLASMA (PRP) AGAINST CONTROL (PLATELET POOR PLASMA) IN THE TREATMENT OF VASCULOGENIC ERECTILE DYSFUNCTION PRELIMINARY RESULTS

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INTRODUCTION AND OBJECTIVE: Platelet-rich plasma (PRP) is an autologous component derived from the patient's own blood, with a high concentration of platelets. There is conflicting evidence regarding the efficacy and safety of this preparation for the treatment of erectile dysfunction. The primary objective of this study is to evaluate the efficacy of intracavernous injection of PRP in the treatment of vascular erectile dysfunction in comparison to control measured by the improvement in the IIEF-EF score after 28 weeks.

METHODS: PRePED is a randomized, double-blind controlled trial (NCT04502875) that compares the administration of 6 weekly injections of PRP versus control in patients with moderate or severe vasculogenic erectile dysfunction who are non-responders to PDE5i. PRP obtained by apheresis had a standard platelet mass for all patients of 10 uL/ml. Non-responders who have received control enter into a second phase to receive the PRP product. The IIEF-EF, EHS, SEP2 and SEP3 questionnaires, as well as a penile Doppler ultrasound, were used as efficacy tools.

RESULTS: The results of the first 27 patients randomized in the study were analyzed (PRP, 13 patients; control, 14 patients). The mean age of the patients was 58.4 (SD 8.9) years. The interim analysis showed that the rate of responders was much lower than expected and additionally in three patients, plaques in the tunica albuginea were detected during the follow-up. Due to these facts, a futility and safety analysis will be performed and the opinion of the Data Safety Monitoring Board (DSMB) will be sought to decide about the early termination of the trial based on the conditional power of the study to achieve its primary outcome and the detected adverse event. The final results of efficacy and safety will be made public at the late-breaking abstract deadline.

CONCLUSIONS: PRP does not appear to be an effective treatment for patients with moderate or severe ED, in addition to being associated with a risk of plaque formation in the tunica albuginea.

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MP47-02

ENCLOMIPHENE VS. CLOMIPHENE: SAFETY AND TESTOSTERONE LEVELS IN HYPOGONADAL MEN

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INTRODUCTION AND OBJECTIVE: Both clomiphene citrate and its isomer, enclomiphene, have become increasingly widespread within urologic practice; thus, understanding these medications' comparative benefits and risks is crucial for optimizing treatment decisions and providing improved therapeutic options. We sought to investigate the benefits and risks associated with enclomiphene, compared to clomiphene.

METHODS: We retrospectively reviewed patients at our center from 01/01/2021-12/21/2022. All included patients were prescribed clomiphene before switching to enclomiphene. We documented baseline laboratory values before starting clomiphene, followed by subsequent values for each variable in the most recent visit before stopping clomiphene and any noted adverse effects experienced during this time. We next repeated these methods of documenting the same outcomes for the same patients in their most recent visit while taking enclomiphene. Adverse events were defined by 1) depressive thoughts; 2) weak muscle strength; 3) gynecomastia; 4) mood changes; or 5) agitation, as well as changes in estradiol and hematocrit laboratory values. Two-tailed T-Tests were employed using R as well as a regression analysis to estimate the odds ratio (OR) for adverse events between the two therapies.

RESULTS: Among 66 patients, enclomiphene exhibited a median testosterone increase of 166 ng/dl ($p=0.200$) with lower estradiol change than clomiphene (−5.92 pg/ml vs. 17.50 pg/ml, $p=0.001$). Adverse effects were significantly less frequent with enclomiphene, including decreased libido ($p=0.001$), reduced energy ($p=0.044$), and mood changes ($p=0.029$). Regression analysis confirmed lower odds of overall adverse events with enclomiphene ($p<0.05$).

CONCLUSIONS: Our findings demonstrate that enclomiphene provides the same magnitude of improvement in testosterone levels with a lower rate of documented adverse events. These findings support enclomiphene as a comparable treatment option for hypogonadal men while minimizing the risk of adverse effects.

Table 1. Rates of side effects for clomiphene and enclomiphene therapy.

	Clomiphene	Enclomiphene	p-value
Overall Side Effects	31 (47%)	8 (13.8%)	0.001
Decreased Libido	22 (33.3%)	5 (8.6%)	0.001
Erectile Dysfunction	12 (18.2%)	5 (8.6%)	0.122
Fatigue	12 (18.2%)	4 (6.9%)	0.061
Decreased Energy	11 (16.7%)	3 (5.2%)	0.044
Depressive Thoughts	3 (4.5%)	0 (0%)	0.247
Weakness	4 (6.1%)	1 (1.7%)	0.370
Gynecomastia	2 (3%)	0 (0%)	0.498
Mood Changes	6 (9.1%)	0 (0%)	0.029
Agitation	4 (6.1%)	1 (1.7%)	0.370

Table 2. Change in total hormonal levels during clomiphene and enclomiphene therapy.

	Clomiphene, median (IQR)	Enclomiphene, median (IQR)	
	Median	Median	p-value
Change in Testosterone	98.0 (-18.0, 684.5)	166.0 (42.5, 683.0)	0.209
Change in E2	17.5 (4.1, 51.8)	-5.9 (-17.7, 26.8)	0.001
Change in HCT	0.4 (-2.1, 6.0)	0 (-1.8, 42.6)	0.855

IQR: interquartile range, E2: estradiol, HCT: hematocrit

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