INPLASY PROTOCOL

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Efficacy of tamoxifen in combination with low dose testosterone undecanoate in the treatment of idiopathic male infertility: a meta-analysis

Guo, B[1]; Liu, JJ[2]; Liu, JG[3].

Review question / Objective: The purpose of this study is to evaluate the effects of tamoxifen plus testosterone undecanoate on conventional sperm parameters, serum gonadotropin and testosterone levels, and pregnancy rate in patients with idiopathic infertility, and to provide evidence-based medicine for tamoxifen combined with testosterone undecanoate.

Condition being studied: Tamoxifen combined with low-dose testosterone has shown good results in the treatment of idiopathic male infertility. Unfortunately, due to the many controversies in the application of testosterone in recent years, the above-mentioned combined application has become very cautious. Research on them is also decreasing year by year. Tamoxifen combined with low-dose testosterone in the treatment of idiopathic male infertility is hope or illusion, which should not be denied because of drug disputes. Instead, a large number of studies and evidence-based medicine should be used to draw reliable conclusions. The purpose of this study is to evaluate the effects of TMX plus TU on conventional sperm parameters, serum gonadotropin and testosterone levels, and pregnancy rate in patients with idiopathic infertility, and to provide evidence-based medicine for tamoxifen combined with testosterone undecanoate.

INTRODUCTION

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METHODS

Participant or population: The patient was diagnosed with idiopathic male infertility.

Intervention: Tamoxifen plus T undecanoate intervention at least for 3 months.

Comparator: Semen analysis performed at baseline was compared with that performed after the intervention. The intervention result of TMX+TU compared to the intervention result of tamoxifen control group.

Study designs to be included: The patient was diagnosed with idiopathic male infertility.

Eligibility criteria: The literature included in this study was not limited by language, and controlled, not-controlled clinical trial ,

Retrospective study, and conference articles was included.

Information sources: PubMed, EMBASE, OVID, Cochrane Library, China National Knowledge Infrastructure (CNKI), Wanfang Database, China Scientific Journals Database (VIP), and China Biomedical Literature Database (CBM).

Main outcome(s): The main： Sperm concentration Sperm total count Sperm motility Sperm total motility Sperm morphology. secondary： LH, FSH, FSF,T, and pregnancy rate.

Quality assessment / Risk of bias analysis: First, we will use the Ottawa-Newcastle scale to assess the quality of all studies, involving the selection of study groups, comparability between groups, and determination of prognosis . Subsequently, the Cochrane bias risk tool was used to evaluate the study quality of the RCTs with tamoxifen as the control group.

Strategy of data synthesis: I2 test was used to test the heterogeneity of the study. If P>.10 and I2≤50%, no statistical difference is considered, fixed effect model will be used. If P ≤ . 1 0 and I2 > 5 0 % , the heterogeneity is considered to be high, and the random effect model will be adopted.

Subgroup analysis: When the literature is adequate, subgroup analysis can be performed by dose or intervention cycle. 1. Dose of administration (e.g. combined testosterone 40mg, 80mg, 120mg, etc.) 2. Intervention period (e.g. 3 months, 6 months, 9 months, etc.).

Sensitivity analysis: According to the outcome indicators of the data, literatures were excluded one by one in terms of method quality, sample size, data missing, measurement, etc., to see whether the heterogeneity was changed. If the results of the sensitivity analysis are consistent, the results are relatively robust. On the contrary, it is not robust and should be treated with caution.

Country(ies) involved: China.

Keywords: Tamoxifen, testosterone undecanoate, empiric medical therapy, idiopathic male infertility, meta-analysis.

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