

Considerations on implementation of the newest treatment for symptomatic uterine fibroids: oral GnRH antagonists.

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Abstract

Novel Gonadotrophin Releasing Hormone (GnRH) antagonist treatments have recently been developed in combination with hormonal add-back therapy, as an oral treatment option for women suffering from uterine fibroids. Registration trials assessing the GnRH antagonist combination preparations with relugolix, elagolix, and linzagolix have assessed treatment efficacy for fibroid related heavy menstrual blood loss in comparison to placebo. Marketing authorization has already been granted by several agencies including those in Europe, the United Kingdom, and the United States. Prior to marketing authorization, the European Medicines Agency recommends that Phase III registration trails should assess treatment efficacy in a representative study population, assess relevant outcomes with a comparison to gold-standard alternative treatment options and that long-term safety data will adequately be collected. In this review, we demonstrate limitations in the trial data generated to date, namely a lack of generalizability due to the restricted population studied, the absence of any comparison to alternative treatment methods, and findings limited to specific subgroups of patients because of the type of outcomes assessed. Symptoms related to uterine fibroids adversely affect many women's quality of life and effective medical treatments are lacking. However, despite the urgent need for effective treatments, it is vitally important that novel drugs, like combination oral GnRH antagonists, undergo sufficiently rigorous evaluation of safety, effectiveness, and cost-effectiveness in a representative population compared with alternative treatment methods before introduction into mainstream clinical practice.

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