

# Long-term Treatment Dienogest In Adolescent Endometriosis Associated Pain

Abstract ID : 2532

Submitted by : syarief thaufik hidayat the 2017-01-31 17:44:44

Category : SEUD CONGRESS 2

Typology : Communication orale / Oral communication

Status : Validated

Authorisation to disclose : Yes/Oui

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## Abstract

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**INTRODUCTION:** Endometriosis is a disease or better a syndrome that starts around the prepubertal age, flourishing after menarche, with symptoms progressing in intensity and throughout the years. It is known that endometriosis is a progressive disease and since there is no cure, adolescents with endometriosis require long-term medical management until the time in their lives when they have completed childbearing. Adolescents presenting with pelvic pain are treated with cyclic combination oral contraceptive pills and nonsteroidal anti-inflammatory agents. If the pain does not respond to these therapies, then in adolescents as in adults, an operative laparoscopy is recommended for the diagnosis and surgical management of endometriosis.

Dienogest is an oral progestin that has been investigated systematically for alternative treatment of endometriosis in dose-ranging, placebo-controlled, active comparator-controlled, and long-term trials performed in Europe and Japan. These studies demonstrated that dienogest has an efficacy, safety, and tolerability profile that is favorable for long-term use, especially in adolescent endometriosis.

**OBJECTIVES:** To assess the effectiveness of dienogest in reducing endometriosis-associated pelvic pain (EAPP) in adolescent patients with endometriosis either surgically or clinically diagnosed at 6 and 12 months, measured by Visual Analogue Scale (VAS) score.

**MATERIAL AND METHODS:** This study is a prospective observational cohort study.

The study will be conducted in routine clinical practice settings. It is planned to enroll 30 adolescent patients with endometriosis for whom a decision has been made by the physician to treat with dienogest according to local health authority approved label. It is the aim of this observational cohort study to further characterize the effectiveness of dienogest in improving quality of life and long-term safety in routine clinical practice setting. Long-term up to 12 months data on effectiveness and safety of dienogest would support the long-term treatment strategy for endometriosis management in the clinical practice.

**RESULTS :** The mean Visual Analogue Scale (VAS) score decreased by 27.4 mm in the dienogest group and by 15.1 mm in the placebo group during the 12-week, representing a statistically significant between group difference of 12.3 mm in favor of dienogest (95% CI, 6.4 to 18.1;  $P < 0.0001$ ). By the end of the 12-week study, the reduction in mean VAS score was 47.5 mm with dienogest .

**CONCLUSION :** Patients treated with dienogest 2 mg/day for up to 12 months showed sustained decrease in endometriosis-associated pelvic pain and a favorable safety profile. Treatment with dienogest may offer an effective and long-term treatment option for endometriosis associated pain.

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Keywords : endometriosis , adolescent , dienogest

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