Clinical Study Synopsis

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1. Abstract

Acronym/Title	Jaydess DUS/ Pharmacoepidemiological study (Drug Utilization Study) of JAYDESS use in routine clinical practice in Sweden.
Report version and date **Author**	Final Report v1.0, 20 AUGUST 2022 Centre for Pharmacoepidemiology Karolinska Institutet
Keywords	levonorgestrel, intrauterine device, health registers, secondary data, drug utilization study.
Rationale and background	Jaydess, a levonorgestrel-releasing intrauterine system containing 13.5 mg of levonorgestrel, was approved for contraception by the European Medicines Agency in 2013. The aim of this post-marketing utilization study is to investigate the characteristics of new users of Jaydess in a "Real World" setting.
Research question and objectives	Primary objectives: 1) describe the characteristics (demographic, clinical, social) of first-time users of Jaydess, 2) estimate the average duration of use. Secondary objectives: study the contraceptive use patterns before and after Jaydess use and evidence of off-label use.
Study design	This observational, population-based study was conducted in 3 parts: 1) a national cohort study using data from the Swedish population-based national registers, 2) a regional cohort study including a subset of women with primary care data from Stockholm county, 3) a medical chart review
Setting	The national registers include information on all Swedish inhabitants (approx.10 million). The regional database includes information on individuals receiving primary health care in Stockholm county, Sweden's largest region. Medical records of Jaydess users were requested from gynecology clinics in teaching hospitals throughout Sweden.

Subjects and study size, including dropouts	The National cohort study population included all women in Sweden with a recorded dispensation of Jaydess between 1 January 2014 to 31 December 2016 (n=38,327), and were followed until 31 December 2020. The Stockholm cohort was a subset of the national cohort (n=13,323). The medical charts for 168 women were reviewed.
Variables and data sources	Data from the following national registers were used: the Prescribed Drug Register (PDR), National Patient Register, Medical Birth Register, and population registers from Statistics Sweden. For the Stockholm cohort, data was added from the Regional Databases on Hospital and Primary Care Diagnoses from Stockholm County. The index date was the date of Jaydess dispensing. Duration of use was estimated based on the index date and one of the following events: an IUD removal procedure code, dispensation of another hormonal contraceptive, the start of pregnancy, or insertion of a copper IUD. From the medical records, data on the indication of use and the insertion and removal dates were extracted.
Results	In the National cohort, the mean age of first-time Jaydess users was 26 (SD±7) years and over 80% received their Jaydess prescription from a midwife. The rate of comorbidities was low, with the most common (2-3%) being diagnoses of depression, anxiety, premenstrual syndrome, menorrhagia, or inflammatory diseases of female genital organs. The duration of Jaydess use was estimated in 83% of women and was a median of 31.3 months. More than 50% of women who continue with hormonal contraception after the index Jaydess used a hormonal IUD. Results from the Stockholm cohort were similar to those of the National cohort. Contraception was the main indication for Jaydess (87%).
Discussion	In this post-marketing utilization study of first-time users of Jaydess in Sweden, we conclude that Jaydess users reflect the general population of reproductive-aged women regarding sociodemographic and health factors. The estimated duration of use was 31 months. Off-label use of Jaydess is likely negligible in clinical practice in Sweden.
Marketing Authorization Holder(s)	Bayer AG 13342 Berlin Germany