ContrAceptive Research on E4 – Health Effects on eveRyday wellbeing (CARE4HER): A post-authorisation, observational, single-arm, open-label study to evaluate health-related quality of life using the Sociedad Española de Contracepción Quality of Life Questionnaire in women prescribed estetrol (14.2 mg)/ drospirenone (3 mg) for contraception.

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Last updated: 05/12/2025

Study Finalised

Administrative details

EU PAS number

EUPAS106503

Study ID

106504

DARWIN EU® study

No

Study countries

- [ ] Germany
- [ ] Hungary
- [ ] Italy
- [ ] Poland

Study description

The impact of contraception on health-related quality of life and the efficacy of the contraceptive method in reproductive-aged women is an important determinant in contraception choice and adherence with contraception methods.

The primary goal of this study is to assess the quality of life of women using E4/DRSP, using the questionnaire developed by the Sociedad Española de Contracepción quality of life (SEC-QoL). This study is an observational, prospective, single-arm, international multi-centre, open-label Phase 4 study to assess QoL using the SEC-QoL, adherence, and clinical safety and tolerability of E4/DRSP in women aged 16 or older without contraindications for E4/DRSP and to linguistically validate the SEC-QoL.

Participants must be prescribed E4/DRSP by a healthcare professional and must initiate E4/DRSP up to 4 weeks after the baseline visit. Study assessments, including the SEC-QoL, will be taken at baseline, 3-months, and 6-months. After the baseline visit, study assessments will be remotely administered.

The Spanish version of the SEC-QoL questionnaire will be translated through a process that ensures linguistic validity into English. The English version will then be translated through the same process that ensures linguistic validity into the appropriate target languages including German, French, Hungarian, Italian, and Polish.

Participant-reported data on demographics, medical history, concomitant medications, contraception use, and the SEC-QoL questionnaire will be collected at the baseline visit via an electronic case report form (eCRF).
During subsequent study assessments at 3- and 6-months, the SEC-QoL questionnaire, pregnancy information, concomitant medications, study status, other forms of contraception utilised, and adherence, will be collected using the participant-reported ePRO module.
AEs will be reported at any time by the participant using the ePRO module.

Study status

Finalised

Research institutions and networks

Institutions

Gedeon Richter

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sydney Willis

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 13/09/2021

Study start date

Actual: 13/03/2023

Date of final study report

Planned: 10/07/2024

Actual: 17/09/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gedeon Richter

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Health related quality of life

Data collection methods:

Primary data collection

Main study objective:

To assess in users of E4/DRSP the change from baseline scores at 3- and 6-months in the menstrual and breast domains of the SEC-QoL Questionnaire.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

DROSPIRENONE

ESTETROL

Population studied

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)

Special population of interest

Women of childbearing potential using contraception

Estimated number of subjects

800

Study design details

Outcomes

o Change from baseline in the 3-item standardised SEC-QoL questionnaire breast domain score after 3 and 6 months. o Change from baseline in the 4-item standardised SEC-QoL questionnaire menstrual domain score after 3 and 6 months. o Change from baseline in individual SEC-QoL questionnaire standardised item scores after 3 and 6 months o Change from baseline in the overall 19-item standardised SEC-QoL questionnaire score after 3 and 6 months o Assess contraceptive efficacy using the Pearl Index o Proportion of self-reported adherent cycles among all participants o Change from baseline in body weight after 3 and 6 months

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Data analysis plan

Scores for the SEC-QoL questionnaire overall and for each domain and the change from baseline in standardised scores will be reported at baseline, the 3-month, and the 6-month follow-up time point summarised by mean, SD, median, first quartile, third quartile, minimum, and maximum. Repeated measures mixed model will be used to formally assess change from baseline to 6 months for each domain using post hoc analyses while adjusting for multiple comparisons (Bonferroni method).

Summary results

Within this study population, at 3-months and 6-months, participants reported a minor increase in both the breast domain and the menstrual domain QoL. Although there were no statistically significant changes nor MWPC at 3-months and 6-months for the SEC-QoL breast and menstrual domains, the SEC-QoL breast and menstrual domain scores were consistent with baseline, with a descriptive trend towards improved QoL. Participants reported an overall increased QoL for individual items on the SEC-QoL primarily for the items in the psychological domain, as well as a statistically significant increase in the combined SEC-QoL score. Importantly, QoL, as measured by the SEC-QoL, was

stable over the course of the study, with a trend for improvement. E4/DRSP contraception was well tolerated.

Data management

ENCePP Seal

> The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No