

# INPLASY

## Impact of vaginal estriol on breast cancer outcomes - a systematic review

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### ADMINISTRATIVE INFORMATION

**Support** - N/A.

**Review Stage at time of this submission** - Data extraction.

**Conflicts of interest** - The authors Petra Stute, Cornelia Betschart and Dorothea Wunder have been part of an interdisciplinary expert board funded by EFFIK SA. Argyrios Kolokythas and Heidrun Janka report no conflict of interest. The authors alone are responsible for the content and writing of the paper.

**INPLASY registration number:** INPLASY202420033

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 February 2024 and was last updated on 07 February 2024.

### INTRODUCTION

**Review question / Objective** Are local vaginal estriol products safe to be used by breast cancer survivors? Do they alter the course of disease?

**Condition being studied** The aim of this review is to study whether the vaginal application of estriol has any effects on breast cancer survivors' course of disease and whether those products could be safely used by this group of patients.

### METHODS

**Participant or population** Inclusion: postmenopausal women (natural, treatment-induced, or surgical menopause) with history of breast cancer. Exclusion: route of application other than intravaginal, study types: other than the ones

mentioned below, women without history of breast cancer.

**Intervention** Inclusion: intravaginal administration of estriol. Exclusion: other routes of estriol administration.

**Comparator** Inclusion: intravaginal administration of estriol of different dosage, intravaginal administration of estradiol, intravaginal administration of lubricant (placebo), no intravaginal administration of any product.

**Study designs to be included** RCTs, controlled studies, head-to-head comparisons, systematic reviews, meta-analyses, quasi-experimental studies (intervention/no control - pre-/post-studies).

**Eligibility criteria** No additional criteria.

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**Information sources** MEDLINE; CINAHL; Embase; Cochrane Library; Web of Science; ClinicalTrials.gov.

**Main outcome(s)** breast cancer recurrence, death, mammographic features, endometrial changes, medication side effects, serum level of estrogens and gonadotropins.

**Quality assessment / Risk of bias analysis** Randomization, blinding, inclusion and exclusion criteria, reporting of dropouts and explanation, intention to treat vs per protocol.

**Strategy of data synthesis** Descriptive analysis.

**Subgroup analysis** No subgroup analysis intended.

**Sensitivity analysis** No sensitivity analysis intended.

**Language restriction** None.

**Country(ies) involved** Switzerland.

**Keywords** menopause; GSM; breast cancer; vaginal estriol; recurrence; serum levels; estradiol; FSH.

**Contributions of each author**

Author 1 - Argyrios Kolokythas.

Author 2 - Dorothea Wunder.

Author 3 - Cornelia Betschart.

Author 4 - Heidrun Janka.

Author 5 - Petra Stute.