

# INPLASY

## Effects of vaginal estriol on genitourinary syndrome of menopause (GSM) - a systematic review

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### ADMINISTRATIVE INFORMATION

**Support** - N/A.

**Review Stage at time of this submission** - Piloting of the study selection process.

**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:** INPLASY202420036

**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** Do local vaginal estriol products help alleviate the genitourinary syndrome of menopause symptoms?

**Condition being studied** The aim of this review is to study whether the vaginal application of estriol has any effects on the genitourinary syndrome of menopause.

### METHODS

**Participant or population** Inclusion: postmenopausal women (natural, treatment-induced, or surgical menopause) with GSM.

Exclusion: route of application other than intravaginal, study types: other than the ones mentioned below. Inclusion: postmenopausal women (natural, treatment-induced, or surgical menopause) with GSM. Exclusion: route of application other than intravaginal, study types: other than the ones mentioned below. Inclusion: postmenopausal women (natural, treatment-induced, or surgical menopause) without history of breast cancer. Exclusion: route of application other than intravaginal, study types: other than the ones mentioned below, women with history of breast cancer.. Exclusion: route of application other than intravaginal, study types: other than the ones mentioned below.

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**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.

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

**Main outcome(s)** pH, vaginal flora, dysuria, urgency, urinary infections frequency, any scales used to assess vaginal atrophy, dyspareunia, sexual life.

**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; vaginal estriol; atrophy; dyspareunia; urinary tract infections.

#### **Contributions of each author**

Author 1 - Argyrios Kolokythas.

Author 2 - Cornelia Betschart.

Author 3 - Dorothea Wunder.

Author 4 - Heidrun Janka.

Author 5 - Petra Stute.