International Platform of Registered Systematic Review and Meta-analysis Protocols

INPLASY

INPLASY202420035

doi: 10.37766/inplasy2024.2.0035

Received: 06 February 2024

Published: 07 February 2024

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Impact of vaginal estriol on endometrial tissue 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 Sabrina Vollrath report no conflict of interest. The authors alone are responsible for the content and writing of the paper.

INPLASY registration number: INPLASY202420035

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

R eview question / Objective Do local vaginal estriol products induce changed in endometrial tissue?

Condition being studied The aim of this review is to study whether the vaginal application of estriol has any effects on endometrial tissue and whether it increases the risk for endometrial hyperplasia or malignancies.

METHODS

Participant or population Inclusion: postmenopausal women (natural, treatmentinduced, or surgical menopause). Exclusion: route of application other than intravaginal, study types: other than the ones mentioned below. **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) sonographically thickened endometrium, need for biopsy, postmenopausal bleeding, endometrial hyperplasia, endometrial cancer

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; endometrium; vaginal estriol; postmenopausal bleeding; hyperlasia.

Contributions of each author

Author 1 - Argyrios Kolokythas. Author 2 - Sabrina Vollrath Author 3 - Dorothea Wunder. Author 4 - Cornelia Betschart Author 5 - Petra Stute.