Efficacy of a new intravaginal gel, containing purified bovine colostrum, in ovariectomized rats with vaginal atrophy

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Introduction

Vaginal dryness due to vaginal atrophy is a common complaint of postmenopausal women, interfering with sexual function and quality of life.

The major hallmarks of vaginal atrophy are:

1) thinning epithelia and
2) local blood flow decrease.

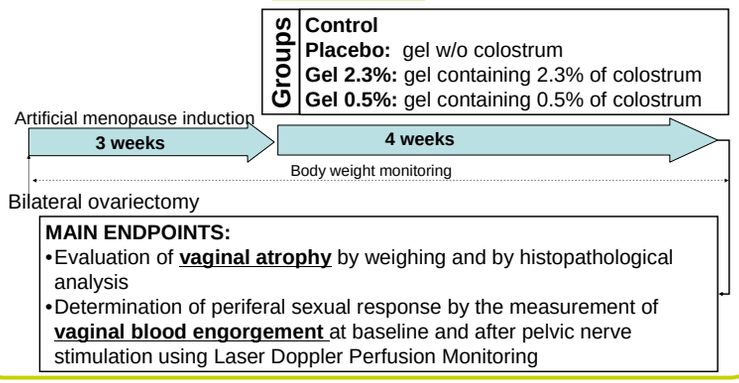
Hormone replacement therapy (HRT) is the only effective therapy but with known risks that leave unmet medical needs.

A new product, an intravaginal gel containing purified bovine colostrum, has been developed for the treatment of vaginal dryness secondary to vaginal atrophy.

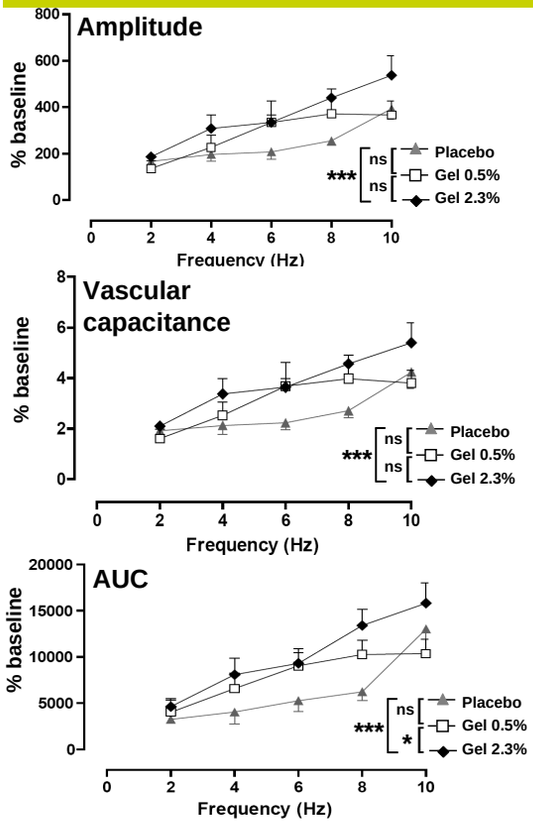
Objective

To investigate the effects of gel application on vaginal atrophy in ovx rats.

Methods

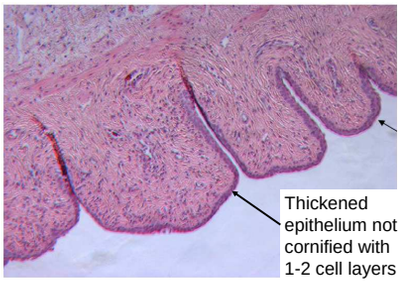


Results

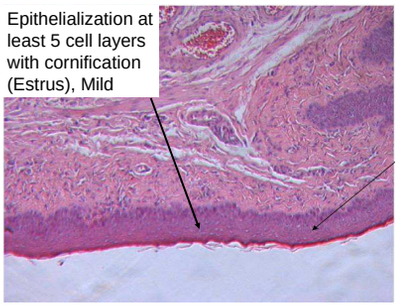


Effect of vaginal gel on vaginal blood engorgement elicited by pelvic nerve electrical stimulations at increasing frequencies: The treatment with Gel 2.3% of Colostrum statistically significant increased all the parameters of vaginal blood engorgement following pelvic nerve stimulation, i.e. maximal amplitude of the response, AUC of the response and vascular capacitance. * P<0.05; ***P<0.001; 2-way ANOVA analysis; ns: non significant

Control (untreated)

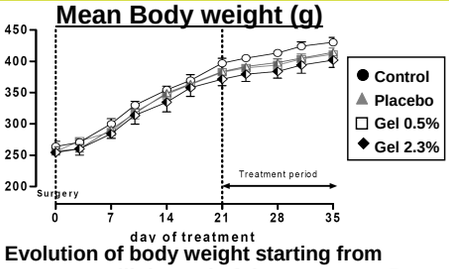


Gel 2.3% of Colostrum



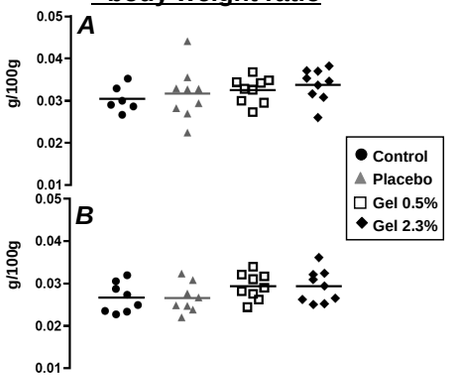
Effect of treatment with vaginal gel on vaginal epithelium: Ovx rats receiving vaginal gel showed a physiological oestrous cycle morphological aspect in the vaginal epithelium; on the contrary, the animals in the control group, showed atrophy in the vagina at the end of treatment.

Mean Body weight (g)



Evolution of body weight starting from surgery untill the end of the treatment: Rat body weights regularly increased during the whole experimental phase with no significant difference between experimental groups.

Vagina (A) and uterus (B) weight - body weight ratio



Evaluation of vagina and uterus weights: Intravaginal treatment with gel containing purified colostrum for 4 weeks in ovx rats did not induce any modification of the vagina and uterus macroscopic aspect. Also vaginal and uterine tissue wet weight and vagina and uterus tissue wet weight normalized to body weight were not modified when compared to placebo.

Conclusion

Twice daily intravaginal treatment with ZP-025 for 4 weeks in an animal model of Vaginal Atrophy

- Induce a physiological oestrous cycle morphological aspect in the vaginal epithelium
- Increased vaginal blood flow engorgement induced by pelvic nerve electrical: stimulation at 2.3% of Colostrum concentration, evidenced by a statistically significant increase in the maximal amplitude, the AUC and the vascular capacitance, while had no significant effect at 0.5 % on all parameters
- Had no effect on uterus and cervix atrophic epithelium
- Had no effect on body weight
- Had no effect on the wet weight of vaginal and uterine tissues