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Title of protocol

Assessment of vulvar skin parameters changes and their correlations with vulvar dryness after the use of Vidermina Lubripiù cream in postmenopausal women.

Principal Investigator: Prof. Filippo Murina

Site of research: Lower Genital Tract Unit-Obst. and Gyn, Dept. –V. Buzzi Hospital-University of the Study of Milan-Milan, Italy

1. INTRODUCTION

The vulva is a unique region of skin that serves as a transition between the cutaneous epithelium of the skin and the mucosa of the female urogenital tract. The barrier function of vulvar skin is weaker than that at other anatomical sites, and vulvar skin has been shown to react more intensely than other skin areas to irritants. The hydrolipidic layer or film, which acts as a protectant, can be damaged by many conditions, like vulvar dermatosis, vulvovaginal infections and menopausal status . According to several population studies, more than half of postmenopausal women suffer from mild or severe vulvovaginal dryness related to specific changes in menopausal hormonal regulation linked to the decreasing level of estrogen, and vulvar skin can be dehydrated with a consequent dryness and vulvar discomfort. There are different ways in which to lubricate a dry vagina, using lubricants – these are similar to natural lubrication and should be applied to the vestibular area and vagina just before sexual intercourse takes place, or vaginal moisturizers which are used two to three times a week and last for up to three days, therefore they do not have to be applied directly before sexual intercourse takes place. Nevertheless, a specific hydrating product is rarely used on the vulvar region.

2. TRIAL OBJECTIVE

The Research Hypothesis for the present study is to prospectively document the impact of Vidermina Lubripiù cream on the vulvar skin parameters in postmenopausal patients complaining vulvar dryness. Vidermina Lubripiù cream

is lubricating, moisturizing, and soothing treatment indicated in case of intimate dryness. Its formulation with emollient complex at 18% and Hyaluronic Acid plays a lubricating and moisturizing action to restore comfort and hydration.
We hypothesize that Vidermina Lubripiù cream for its properties is effective resolving vulvovaginal discomfort related to vulvar dryness in postmenopausal women.

3. OUTCOMES

Outcomes will include:

- Evaluation of vulvar skin parameters regarding the hydration level, pH, and sebum level of the skin surface. The measurements will be performed using the Corneometer® CM 825, Skin-pH-Meter PH 905® and Sebumeter SM815® devices, each with a probe connected to an MDD4 base unit (Courage-Khazaka). We will assess sequential measurements on the middle third of the left and right sides of the labia majora and labia minora. Three repeated measures were taken at each vulvar skin site, and an average value will be calculated.
- Subjective evaluations of vulvar dryness defined as : after 30 days, using a 0-10 point intensity scale (0 = absent, 10= very high)

4. DESCRIPTION OF RESEARCH DESIGN

4.1 Overall Study Plan
This is an open, interventional uncontrolled clinical trial in one cohort of healthy women to be conducted at Lower Genital Tract Unit-Obst. and Gyn, Dept. –V. Buzzi Hospital-University of Milan-Milan, Italy.

4.2 Study Duration
It is expected this investigator-initiated research study will be completed approximately 2-3 months following initial approval by the Institutional Ethical Board.

4.3 Institutional Ethical Board Approval (IEB)
Prior to conducting any study-related procedures, the Principal Investigators will each obtain written approval from their respective IEB for the informed consent form, protocol, recruitment materials, and any written information provided to Subjects pertaining to the procedure.

5. Selection and Withdrawal of Subjects

The study population will include healthy women without any vulvovaginal condition.

5.1 Subject Inclusion Criteria

All criteria below must be met to be eligible for study participation.

- Women between 40–70 years with physiological menopause
- Absence of contraindications to the proposed intimate cleanser product
- Read and signed informed consent.

5.2 Subject Exclusion Criteria

Subjects who meet any of the following criteria shall be excluded:

-Active vulvo-vaginal infections at the time of their gynecological examination.
-Genital bleeding of unknown origin
-Active vulvo-vaginal infection at the time of their gynecological examination
-Vulvar dermatosis or other vulvar disease
-Lesions in the vulva that have not been evaluated
-Unwillingness to wash out one's usual intimate cleanser
-Patients concomitantly included in different interventional clinical trials.
-Unwillingness to provide the informed consent to the trial.

5.3 Subject Withdrawal Criteria

The Principal Investigator may discontinue a subject's participation in the study at any time if it is considered in the subject's best interest to do so. Such a decision may be precipitated by adverse events, new onset illness, clinically important changes in vital signs, physical examinations, or laboratory tests. Subjects who are noncompliant with study procedures and visits may also be withdrawn by the Principal Investigator. Subjects may withdraw from participation in the study at any time for any reason. A subject's decision to withdraw will not cause the subject to lose any benefits to which she is entitled. A subject who withdraws prematurely from the study will return to the clinic as soon as possible to undergo the final visit evaluations.
If a subject prematurely withdraws or is withdrawn from study participation, the reason for the withdrawal must be recorded on the case report form (CRF).
Record the primary reason for premature withdrawal according to the following categories:

• Adverse Event: Subject experiences an intolerable event, which may or may not be related to the study medication
• Withdrawn Consent: Subject withdraws from study participation for personal reasons (exclude adverse experience before indicating this category)
• Concomitant Medication Violation: Subject initiates, discontinues, or changes dosing regimen of concomitant medication in violation of the protocol, which, in the judgment of the Principal Investigator, may adversely affect evaluation of safety

• Lost-to-Follow-up: Subject does not return for evaluation and no further contact is made by the Subject after three documented phone or email attempts and a final attempt by certified mail.
• Other: Any reason that does not fit in the above 4 categories: the reason will also be recorded on the CRF.

6. Clinical Procedures

Clinical procedures throughout the study are described in the sections below.

6.1 Informed Consent

Each potential study Subject must provide written informed consent and authorize release of her protected health information before any study procedure is conducted.

6.2 Study Day 0: Subject Screening (Visit 1)

Before initiation of any study procedures, Subjects will be fully informed of the study plan. Each potential Subject will be required to read and to indicate her understanding by signing and dating the ICF prior to initiation of any screening procedures. Subject meeting inclusion and exclusion criteria will be enrolled.
For all the participants, the previous clinical history, age, marital status, ethnic origin, the use of contraception, and history of medication and vaginal infections will be recorded. Following consent to participate, all subjects will undergo an evaluation of vulvar skin parameters regarding the hydration level, pH, and sebum level of the skin surface.
All enrolled women subsequently will receive the Vidermina Lubripiù cream , and the women will be asked to use the product once daily for 30 days.

6.3 Study Day 30 ± 2 days: Follow-Up (Visit 2)

-Vulvar skin parameters evaluation regarding the hydration level, pH, and sebum level of the skin surface will be repeated.
- Subjective evaluations of vulvovaginal dryness after 30 days, using a 0-10 point intensity scale (0 = absent, 10= very high)

6. Statistical Methods

6.1 Determination of Sample Size

The sample size of 20 subjects was chosen for this study based on this being a pilot study, and this sample size will be enough to prospectively document changes in vulvar skin parameters in this cohort of women.

References.

-Van der Meijden WI, Boffa MJ, ter Harmsel WA, et al. European guideline for the management of vulval conditions. J Eur Acad Dermatol Venereol. 2017;31(6):925-941

-Goncharenko V, Bubnov R, Polivka J Jr, Zubor P, Biringer K, Bielik T, Kuhn W, Golubnitschaja O. Vaginal dryness: individualised patient profiles, risks and mitigating measures. EPMA J. 2019 Mar 2;10(1):73-79.