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An open, single center, clinical investigation to evaluate the efficacy and safety of woman ISDIN Vaginal Moisturizer on symptomatic vaginal atrophy in post menopausal woman

Submission date
12/01/2024

Recruitment status
No longer recruiting

Registration date
19/01/2024

Overall study status
Completed

Last Edited
12/05/2025

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Currently, it has been proven that Vaginal Moisturizers effectively alleviate and improve mild to moderate symptoms of vulvovaginal atrophy. These symptoms include issues like vaginal dryness, insufficient lubrication, and discomfort or pain during sexual intercourse. In light of this, a study is being planned to assess how effective the Woman ISDIN Vaginal Moisturizer is in relieving symptoms related to vaginal dryness or atrophy caused by insufficient hydration, with a specific focus on potential discomfort or pain during sexual activity.

Who can participate?
Diagnosed postmenopausal women patients over 18 years old with menopause symptoms women can participate in this study.

What does the study involve?
The study involves three visits to the hospital. The second visit is scheduled four weeks after the initial one, and the third and final visit occurs 12 weeks after the first visit. During these visits, participants are asked about basic information like their weight and age, general health details, any illnesses they've had, and the treatments they received. They also provide feedback on the intensity of symptoms such as dryness and itching, share information about vaginal atrophy, and complete questionnaires related to their sexual and menopausal health, product usability, and overall quality of life. Additionally, participants undergo a vaginal examination. Throughout the 12 weeks, any discomfort experienced is documented for further analysis.

What are the possible benefits and risks of participating?
Participating in this research may offer potential benefits by contributing to the development of new products aimed at alleviating the discomfort associated with vulvovaginal atrophy in the post-menopausal period in the future. However, it's important to note that participants may not directly gain any immediate health benefits from taking part in this clinical research.

When considering the risks associated with this study, it's crucial to mention that the investigational product has demonstrated safety since its introduction in Spain in 2012, following the provided instructions. As outlined in the instructions for use document, some individuals may experience vaginal irritation or discomfort while using the product. As with any vaginal product, there is an expected possibility that individuals sensitive to certain components may encounter events related to hypersensitivity or irritation. It's important to note that severe, unpredictable, and life-threatening allergic reactions are exceptionally rare but cannot be entirely ruled out.

Where is the study run from?
Diatrecnon (Spain)

When is the study starting and how long is it expected to run for?
September 2021 to April 2023

Who is funding the study?
ISDIN (Spain)

Who is the main contact?
Rafael Sanchez Borrego, rschez.borrego@diatros.com

Contact information

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Public, Scientific

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Additional identifiers

Protocol serial number
ISD-WO-VAGINAL-01-2021

Study information

Scientific Title
An open label, observational, non-interventional, unicentric, clinical investigation to evaluate the efficacy and safety of woman ISDIN Vaginal Moisturizer on symptomatic vaginal atrophy in 43 post menopausal woman during 12 weeks in the alleviation of vaginal atrophy symptoms

Acronym
VAMOS Study

Study objectives
The study aim is to evaluate the efficacy of WOMAN ISDIN® Vaginal Moisturizer in decrease of the most bothersome symptom of vaginal atrophic at 12 weeks of treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/03/2022, COMITÉ ÉTICO DE INVESTIGACIÓN con Medicamentos (CEIm) GRUPO HOSPITALARIO QUIRÓNSALUD-CATALUNYA (c/ Pedro i Pons 1, SANT CUGAT DEL VALLÈS (Barcelona), 08195, Spain; +34 93 565 60 00 Ext 5935; ceic.idcsa.cat@idcsalud.es), ref: 2022/15-GIN-CMT

Primary study design
Observational

Study design
Prospective observational unicentric and open label 12 weeks study duration

Study type(s)
Quality of life, Safety, Efficacy

Health condition(s) or problem(s) studied
Efficacy and safety of Woman ISDIN® Vaginal Moisturizer in the alleviation of vaginal atrophy symptoms

Interventions

The treatment period will last 12 weeks for each patient, during which time they will use the investigational product as directed in the instructions. Therefore, it is expected to carry out 3 visits per patient at the investigational center; 1 baseline selection visit where the study products are provided, 2 follow-up visits every 1 and 3 months after baseline visit.

Intervention Type
Other

Primary outcome(s)
1. Patient's perception of the most bothersome symptom at baseline and 12 weeks using Patient's perception of vaginal discomforts evaluation

Key secondary outcome(s)
1. Patient's perception of the most bothersome symptom at baseline and 4 weeks using Patient's perception of vaginal discomforts evaluation
2. Patient's perception of the vaginal discomforts at baseline, 4 and 12 weeks of treatment using Patient's perception of vaginal discomforts evaluation.
3. Average score of Vaginal Health Index (VHI) at baseline, 4 and 12 weeks.
4. pH evaluation evaluated by pH strips at baseline, 4 and 12 weeks.
5. Patient's global assessment of overall satisfaction at 4 and 12 weeks of treatment.
6. Improvement of sexual function through questionnaire Female Sexual Function Index (FSFI) at baseline, 4 and 12 weeks.
7. Improvement of quality of life through Cervantes scale’s questionnaire at 4 and 12 weeks.
8. Local tolerability at the application site evaluated by the patient at 4 and 12 weeks.
9. Cosmetic, satisfactory and efficacy questionnaire at 4 and 12 weeks.
10. Safety: collection of S/AE emerged as consequence of the product application and any other adverse event occurred during the study.

Completion date
12/04/2023

Eligibility

Key inclusion criteria
1. Woman aged 18-75 years old.
2. Postmenopausal woman (≥12 months since last spontaneous menstrual period, or having 6 months of spontaneous amenorrhea with serum Follicle Stimulating Hormone (FSH) levels >40 IU /L), both natural post menopause or iatrogenic conditions.
3. At least one of the following symptoms of vaginal atrophy, assessed as moderate to severe:
3.1. Vaginal dryness,
3.2. Vulvovaginal irritation/itching experienced at least weekly within the past 30 days,
3.3. Vaginal pain associated with sexual activity at least once monthly.
4. Vulvovaginal atrophy with VHI <15.
5. Vaginal pH >5.0
6. Women with active sex life.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Female

Total final enrolment
43

Key exclusion criteria
1. Patients that present clinical signs of vaginal infections and other vaginal disorders.
2. Patients are currently using product for Vulva Vaginal Dryness (VVD) or VDA.
3. Patients in previous treatment with either oral or topical hormonal products within 1 month. Use of estrogens/progestins products (vaginal, oral, pellet, transdermal, etc.) in the 4 weeks to 6 months (depending on the product used) prior to study entrance.
4. Positive history of hypersensitivity to any component of the medical device.
5. Presence of other malignancies including cervical, ovarian, and uterine cancers.
6. Operative history of hysterectomy or oophorectomy.
7. Current use of medication for urogynecologic problems.
8. Unexplained vaginal bleeding.
9. Pregnant or breastfeeding.
10. Not having performed any regenerative gynecology technique (laser, radiofrequency or filler insertion).

Date of first enrolment
04/05/2022

Date of final enrolment
18/01/2023

Locations

Countries of recruitment
Spain

Study participating centre
DiaTrecnon SLP
Cl. Vilana, 12-Dpcho.168,
Barcelona
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Sponsor information

Organisation
Isdin (Spain)

ROR
https://ror.org/04dg86p75

Funder(s)

Funder type
Industry

Funder Name
ISDIN

Results and Publications

Individual participant data (IPD) sharing plan
The data set generated during and/or analyzed during the current study are not expected to be made available due to ISDIN policy and confidentiality

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/05/2025	12/05/2025	Yes	No
Other files	Product instruction leaflet		18/01/2024	No	No