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A study of a new treatment for vaginal dryness, pain and other symptoms associated with menopause

Submission date
13/08/2026

Recruitment status
No longer recruiting

Registration date
13/08/2026

Overall study status
Completed

Last Edited
13/08/2026

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Vaginal dryness, discomfort and pain during sexual intercourse are common during and after the menopausal transition. These symptoms are caused by changes in the vaginal tissues associated with lower estrogen levels and can affect sexual health and quality of life. Hormone treatments can be effective, but they may not be suitable or preferred by all women.
Extracellular vesicles are very small particles naturally released by cells. They carry proteins and other biologically active substances that are involved in communication between cells and may support tissue repair and regeneration. This pilot study aims to assess the safety and potential effects of a treatment containing extracellular vesicles derived from mesenchymal stromal cells in women with symptoms of vulvovaginal atrophy.

Who can participate?
Peri- and postmenopausal women with clinically confirmed symptomatic vulvovaginal atrophy can participate. Symptoms may include vaginal dryness, reduced lubrication, pain during sexual intercourse, reduced sexual desire or other changes in sexual function.

What does the study involve?
Participants receive a single treatment containing extracellular vesicles derived from mesenchymal stromal cells from three different tissue sources: umbilical cord, adipose tissue and dental pulp. A total volume of 1 ml containing 3 billion extracellular vesicle particles is injected into the vaginal tissue using a series of small injections after application of a local anaesthetic cream. No additional treatment specifically for vulvovaginal atrophy is given during the 12-month follow-up period.
Participants are assessed before treatment and at 1, 3, 6 and 12 months after treatment. The assessments include vaginal pH, vaginal tissue health and maturation, sexual function using a standardized questionnaire, and monitoring for any treatment-related side effects.

What are the possible benefits and risks of participating?
The treatment may improve vaginal health and symptoms associated with vulvovaginal atrophy, although individual benefit cannot be guaranteed. As the treatment involves injections into the

vaginal tissue, participants may experience temporary local discomfort associated with the procedure. Participants are monitored for treatment-related adverse events throughout the 12-month follow-up period.

Where is the study run from?
Dr Demianenko LLC (Ukraine)

When is the study starting and how long is it expected to run for?
August 2023 to January 2025

Who is funding the study?
Good Cells LLC (Ukraine)

Who is the main contact?
Dr Inna Gordiienko, i.gordienko@goodcells.com

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Study information

Scientific Title
One-year outcomes of mesenchymal stromal cell-derived extracellular vesicle therapy in women with vulvovaginal atrophy: a prospective pilot study

Study objectives
To evaluate the safety and therapeutic potential of a mesenchymal stromal cell-derived extracellular vesicle (EV) complex in peri- and post-menopausal women with vulvovaginal atrophy (VVA), and to assess its effects on vaginal epithelial maturation, vaginal health, vaginal pH, and sexual function over a 12-month follow-up period.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/03/2023, Bioethics Commission of the Institute of Genetic and Regenerative Medicine, State Institution National Scientific Center M.D. Strazhesko Institute of Cardiology, Clinical and Regenerative Medicine of the National Academy of Medical Sciences of Ukraine (5 Svyatoslava Khorobroho St., Kyiv, 03151, Ukraine; +380 (0)44 275 66 22; stragh.cardio@gmail.com), ref: 9/03-23

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Vulvovaginal atrophy (VVA) in peri- and postmenopausal women

Interventions
Participants received a single intramucosal administration of 1 ml of an extracellular vesicle (EV) complex containing 3 × 10^9 particles suspended in physiological saline. The EV complex consisted of EVs derived from allogeneic mesenchymal stromal cells from three tissue sources: umbilical cord, adipose tissue, and dental pulp. EVs from the three MSC sources were combined at a 1:1:1 ratio based on particle number. The preparation was administered using a micropapular injection technique following topical application of lidocaine cream. No additional VVA-directed treatment was administered during the 12-month follow-up.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Mesenchymal stromal cell-derived extracellular vesicle (EV) complex

Primary outcome(s)
1. Vaginal pH measured using indicator strips at baseline and 1, 3, 6 and 12 months after treatment

2. Desire, arousal, lubrication, orgasm, satisfaction, and pain measured using the Female Sexual Function Index (FSFI) at baseline and 1, 3, 6 and 12 months after treatment

3. Safety and tolerability measured using the incidence, type and severity of treatment-related adverse events assessed by participant reporting and clinical evaluation at throughout the 12-month follow-up period

Key secondary outcome(s)
1. Vaginal epithelial maturation measured using the proportions of parabasal, intermediate, and superficial epithelial cells in vaginal cytology samples at baseline and 1, 3, 6 and 12 months after treatment

2. Vaginal health measured using elasticity, fluid volume, vaginal pH, epithelial integrity and moisture at baseline and 1, 3, 6 and 12 months after treatment

Completion date
31/01/2025

Eligibility

Key inclusion criteria
1. Peri- or postmenopausal women with clinically confirmed vulvovaginal atrophy (VVA)
2. Presence of symptomatic VVA, including one or more of the following symptoms: vaginal dryness, dyspareunia, reduced lubrication, decreased sexual desire, diminished or absent orgasm, or pain during sexual intercourse.

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
48 Years

Upper age limit
53 Years

Sex
Female

Total final enrolment
10

Key exclusion criteria
1. Stress urinary incontinence
2. Vaginismus
3. Vulvovaginal or urinary tract infections
4. HPV + patients
5. Genital bleeding of unknown origin
6. Hormone-dependent malignancies
7. Previous vulvovaginal or urogynecological surgery
8. Uncontrolled systemic diseases
9. Coagulation disorders
10. History of hypertrophic scar formation

Date of first enrolment
03/08/2023

Date of final enrolment
29/01/2024

Locations

Countries of recruitment
Ukraine

Study participating centre
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Sponsor information

Organisation
Good Cells LLC

Funder(s)

Funder type

Funder Name
Good Cells LLC

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available