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The effect of Deflagyn vaginal gel in premenopausal women with precancerous changes of the cervix

Submission date 21/06/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 12/12/2022	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 14/07/2025	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
The purposes of the study are to assess the effect of the vaginal gel Deflagyn in patients with a finding of abnormal cells (HSIL) that line the outer part of the womb (cervix), and to prove the relationship between cytokines and progression or regression of a cervical lesion (HSIL).

Who can participate?
Women aged between 25 and 50 years old

What does the study involve?
The treatment is conducted according to worldwide standards after 3 months of Deflagyn treatment. There will be no biopsy performed before vaginal gel usage, as we want to see the pure effect of Deflagyn. If a biopsy is undertaken, it will bias the results. Biopsies will be performed after 3 months of vaginal Deflagyn application according to clinical standards if the colposcopy lesion is still visible. Before treatment with Deflagyn the patients will be given a questionnaire with 13 questions to answer about cervical cancer risk.

What are the possible benefits and risks of participating?
A possible benefit of this vaginal gel is that patients will be cleared of HPV and will show a regression of the precancerous lesions. This may avoid the necessity to perform surgical excision of part of the cervix and therefore the full functionality of the cervix will continue.
There are no risks for participants. Only well-defined colposcopic lesions on the ectocervix with a visible squamocolumnar junction are included in the study in order to exclude the risk of invasive cancer.

Where is the study run from?
Medline Clinic (Uzbekistan)

When is the study starting and how long is it expected to run for?
June 2022 to October 2026

Who is funding the study?
1. Investigator initiated and funded
2. Deflamed International S.R.O. (Czechia)

Who is the main contact?
1. Dr Yusupova Shahnoza shahnoza.yusupova90@gmail.com
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Cytokines in patients with HSIL, HPV positive >25 years old and <50 years old before and after Deflagyn vaginal gel compared to a control group with normal cytology (NILM)

Study objectives
The primary objective is to evaluate the effect of vaginal gel Deflagyn on cytokines. Changes in cytokine levels are analyzed by using a multiplex bead-based immunoassay. The secondary objective is to analyze the effect of vaginal gel Deflagyn on HPV, cytology, colposcopic appearance, bacteriology, methylation analysis and pH in the vagina.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/06/2022, Ethical Committee at Tashkent Medical Academy (14, H.Olimjon str, Urgench, Khorezm region, 220100, Uzbekistan; +998 (0)995649170; ttaurgfil@umail.uz), ref: 01 /2016

Study design
Prospective cohort study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Local treatment of cervical precancerosis, prevention of cervical cancer

Interventions
Local treatment of precancerosis of the cervix with vaginal gel Deflagyn. The control group consists of patients with a normal PAP smear independent of the HPV test. In the study group (HSIL, HPV positive), patients will be treated with intravaginal self-administrated vaginal gel Deflagyn containing 10.0 mg of highly dispersed silicon dioxide, 24.8 mg of citric acid, and 0.25 mg of selenium per administration (5 ml). The vaginal gel should be applied daily, deep inside the vagina using a single-use applicator during 3 × 28-day courses. The sponsor of the investigational device is Deflamed International S.R.O. Before treatment with Deflagyn the patients will be given a questionnaire with 13 questions to answer about cervical cancer risk.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Deflagyn

Primary outcome(s)
Cytokine levels measured using multiplex immunoassay on analyzer Luminex 200 System before and after usage of Deflagyn

Key secondary outcome(s))

1. High-risk human papillomavirus (HR-HPV) positivity measured using PCR before and after treatment with Deflagyn
2. Cervical smear cytology measured using a liquid-based Pap-test before and after treatment with Deflagyn
3. Presence of cervical lesions diagnosed using colposcopy before and after treatment with Deflagyn
4. Lactobacillus in the cervical smear measured using scanning electron microscopy before and after treatment with Deflagyn
5. PH of cervical mucus measured using pH strips before and after treatment with Deflagyn
6. Assessment of cervical cancer risk measured using a questionnaire before treatment with Deflagyn
7. DNA methylation analysis measured using sequencing before and after treatment with Deflagyn

Completion date
24/10/2026

Eligibility

Key inclusion criteria
1. HPV+, HSIL and control group
2. Squamo-cylindric junction visible in colposcopy
3. Acetic acid white lesion <50% of the ectocervix
4. Aged 25 years old and over to <50 years old (premenopausal)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 years

Sex
Female

Key exclusion criteria
1. Cancer
2. Immunodeficiency (HIV)
3. Smoking
4. Pregnancy
5. Menometrorrhagia
6. Inflammatory and viral genital diseases (syphilis, gonorrhea, adnexitis)

Date of first enrolment
24/12/2022

Date of final enrolment
24/07/2025

Locations

Countries of recruitment
Uzbekistan

Study participating centre
Medline Clinic
Pachlavana Machmuda Sreet 220
Urgench
Uzbekistan
220100

Study participating centre
The Med Layn clinic (Sarvinoz medservis)
Pahlavon Mahmud 220
Urgench
Uzbekistan
-

Study participating centre
The oncogynecology department of the regional oncological dispensary
A. Bahodirhon 176
Urgench
Uzbekistan
-

Study participating centre
Clinical bases (clinic "Health Center")
Al-Xorazmiy 75
Urgench
Uzbekistan
-

Study participating centre
Clinic "Zurriyot Shifo
Eshlik 11

Urgench
Uzbekistan
-

Study participating centre
Clinic "Sherzodbek Shifo" of the Department of Obstetrics and Gynecology of the Urgench branch of the Tashkent Medical Academy
Mustaqillik 12
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Sponsor information

Organisation
Nika Farm

Organisation
Gynial AG

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
Deflamed International S.R.O.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding authors (Dr Kudrat Jumaniyozov, kudrat.jumaniyazov@minzdrav.uz, Prof Attila Major, cabinetfemina@outlook.com and Dr Aleksandra Riger, riger96@mail.ru) on reasonable request

IPD sharing plan summary
Available on request