

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

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| Submission date 21/06/2022 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 12/12/2022 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 14/07/2025 | Condition category Cancer | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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
2. Dr Kudrat Jumaniyozov kudrat.jumaniyazov@minzdrav.uz

Contact information

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

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 measure

Cytokine levels measured using multiplex immunoassay on analyzer Luminex 200 System before and after usage of Deflagyn

Secondary outcome measures

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

Overall study start date

10/06/2022

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

Age group

Adult

Lower age limit

25 Years

Sex

Female

Target number of participants

Target number of participants 77 active with HSIL with Deflagyn treatment and 38 controls with normal cytology without Deflagyn treatment .

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

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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

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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

Horezm region, Kushkupir district

Uzbekistan

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Study participating centre

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Sponsor information

Organisation

Nika Farm

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Sponsor type

Industry

Organisation

Gynial AG

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Sponsor type

Industry

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

Funder Name

Deflamed International S.R.O.

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

24/04/2027

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