

# The dialyzable leukocyte extract activates cervical innate immunity in HPV-infected patients with CIN 1

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
11/01/2016	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
26/01/2016	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
30/11/2020	Cancer	

## Plain English summary of protocol

### Background and study aims

Cervical carcinoma (cervical cancer) is one of the major public health problems in the world; in Mexico it is the second leading cause of death in women. Almost all cases of cervical cancer are caused by the human papilloma virus (HPV). It is a very common virus that can be passed on by sexual contact. It usually takes many years to develop. Before the cancer actually develops, the cells of the cervix often show changes known as cervical intraepithelial neoplasia (CIN). Patients with CIN1 cells are unlikely to develop cancer and the abnormal cells will often disappear without treatment. However, they can also progress to CIN2 or CIN3, at which point, the risk of developing cervical cancer increases. Removing the cells at these stages is usually recommended. Some 50% of adolescents and young adults can be infected with HPV within the first few years of starting a sex life. 90-95% of infections are resolved thanks to the immune system. However, in certain cases some infected women become long-term infected (viral persistence) and suffer from chronic cervical inflammation, which increases the risk of cervical intraepithelial neoplasia and cancer. It is, therefore, very important to provide timely treatment for women with precancerous lesions (CIN), including the use of immunotherapies that enable the proper functioning of the immune system against viral persistence. Dialyzable leukocyte extract (DLE) can activate the immune response against infections or neoplasias. The main objective of this work was to document the effect of DLE immunotherapy on the immune response of patients with cervical lesions.

### Who can participate?

Women diagnosed with CIN1.

### What does the study involve?

First of all, participants undergo a medical history, assessment of clinical symptoms, cervical cytology, colposcopy and cervical biopsy. They are then randomly allocated to one of two groups. Those in group 1 are given DLE for one month. Those in group 2 are given a placebo (dummy treatment) for one month. After the months treatment is complete, each participant undergoes another assessment of their clinical symptoms, a colposcopy and a cervical biopsy.

**What are the possible benefits and risks of participating?**

Possible benefits to participating in this study include almost total remission of the clinical symptoms particularly those associated with cervicitis (inflammation of the cervix) and abdominal pain, remission of cervical lesions and free treatment.

**Where is the study run from?**

The National Polytechnic Institute, Clinic of Gynecology and Obstetrics, Hospital General de Milpa Alta, Center for Research and Advanced Studies and Laboratory Farmainmune (Mexico City, Mexico)

**When is the study starting and how long is it expected to run for?**

January 2013 to December 2013

**Who is funding the study?**

National Council of Science and Technology, Mexico

**Who is the main contact?**

Dr Guillermo Perez Ishiara  
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## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Guillermo Perez Ishiara

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**Contact details**

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## Additional identifiers

**Protocol serial number**

N/A

## Study information

**Scientific Title**

The dialyzable leukocyte extract activates cervical innate immunity in HPV-infected patients with CIN 1

## **Study objectives**

If the dialyzable leukocyte extract (DLE) has an anti-inflammatory effect, the DLE treatment of HPV infected patients with preneoplastic lesions would regulate the cervical immune response, modifying the clinical and histopathological signs of the disease.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethics Committee of the National School of Medicine and Homeopathy from National Polytechnic Institute (Mexico), 11/01/2015, ref: 0152013

## **Study design**

Randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Low-grade cervical intraepithelial neoplasia (CIN-1)

## **Interventions**

A total of 54 Mexican women patients with cervical cytological diagnosis of CIN 1 were included in this study. After signing the consent form, patients were evaluated by clinical signs and symptoms. Then, colposcopy and biopsy were taken to confirm the Intraepithelial Low-Grade Lesion (CIN 1). Patients were randomly divided into two groups: placebo group and DLE-treatment group. Each group was treated in a double blind random way using 3 units of placebo or DLE per week, during one month. Then, patients were clinically evaluated and explored again by colposcopy. Cervical samples were taking for both, histopathological and immuno-histochemical assays. HPV genotyping were done from biopsy samples obtained before treatment.

## **Intervention Type**

Biological/Vaccine

## **Primary outcome(s)**

1. The colposcopical characteristics of cervical lesions using the iodine test, qualitatively measuring the cervical localization and extension of the lesions
2. Evaluation of clinic signs and symptoms considering the Mexican NOM-014-SSA2-1994 for the prevention, detection, diagnosis, control and treatment of Cu CA

Measured before and after one month of treatment.

## **Key secondary outcome(s)**

1. Histopathological characterization of biopsies lesions
2. Immunohistochemical evaluation of immunological markers related to innate immune response

Measured before and after one month of treatment.

**Completion date**

31/12/2013

## Eligibility

**Key inclusion criteria**

Women between 20 and 60 years old with cytological CIN 1 diagnosis.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Total final enrolment**

54

**Key exclusion criteria**

1. Women under 20 and over 60 years old
2. Pregnant.
3. Diabetic
4. With autoimmune or infectious diseases
5. Patients with cervicitis under treatment
6. Diagnosed with cervical cancer in situ or invasive
7. With pre-malignant CIN III lesions whose biopsy shows positive margins
8. With pre-malignant lesions of cervical cancer that have been treated with invasive methods

**Date of first enrolment**

02/01/2013

**Date of final enrolment**

20/12/2013

## Locations

**Countries of recruitment**

Mexico

**Study participating centre**

**National Polytechnic Institute (Instituto Politécnico Nacional)**

Guillermo Massieu H. 239

Colonia La Escalera

Gustavo A. Madero

Mexico City

Mexico

07320

**Study participating centre**

**Clinic of Gynecology and Obstetrics**

Carlota Armero 5 B -20

Colonia CTM Culhuacan

Delegacion Coyoacán

Mexico City

Mexico

04480

**Study participating centre**

**Hospital General de Milpa Alta**

Bvd. José López Portillo 386

Colonia Santa Cruz Milpa Alta

Mexico City

Mexico

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**Study participating centre**

**Center for Research and Advanced Studies**

Department of Genetics and Molecular Biology

Av. Instituto Politécnico Nacional 2508

Colonia San Pedro Zacatenco

Mexico City

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**Study participating centre**

**Laboratory Farmainmune**

Naranjos 129

Colonia Petrolera

Delegacion Azcapotzalco

Mexico City  
Mexico  
02480

## Sponsor information

### Organisation

National School of Medicine and Homeopathy from National Polytechnic Institute (Mexico).

### ROR

<https://ror.org/059sp8j34>

## Funder(s)

### Funder type

Government

### Funder Name

Consejo Nacional de Ciencia y Tecnología

### Alternative Name(s)

Consejo Nacional de Humanidades, Ciencias y Tecnologías, Consejo Nacional de Ciencia y Tecnología, National Council of Humanities, Sciences and Technologies, Mexican National Council of Science and Technology, National Council for Science and Technology (CONACyT), National Council of Science and Technology, Mexico, Conahcyt

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

Mexico

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/10/2017	30/11/2020	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes