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

Submission date
11/01/2016

Recruitment status
No longer recruiting

Registration date
26/01/2016

Overall study status
Completed

Last Edited
30/11/2020

Condition category
Cancer

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

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 Ishiwara
ishiwaramx@yahoo.com.mx

Contact information

Type(s)
Scientific

Contact name
Dr Guillermo Perez Ishiwara

ORCID ID
https://orcid.org/0000-0001-9368-3717

Contact details
Escuela Nacional de Medicina y Homeopatía-IPN
239 Guillermo Massieu Helguera Street
La Escalera
Mexico City
Mexico
07320
+52 (01) 5729 6300 Ext. 55534.
ishiwaramx@yahoo.com.mx

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 preneoplasic 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
Blvd. José López Portillo 386
Colonia Santa Cruz Milpa Alta
Mexico City
Mexico
12000

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
Mexico
07360

Study participating centre
Laboratory Farmainmune
Naranjos 129
Colonia Petrolera
Delegacion Azacapotzalco

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 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?
Results article	results	01/10/2017	30/11/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes