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Recurrent and nonrecurrent condyloma treatment

Submission date	Recruitment status	[_] Prospectively registered
23/09/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/10/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/10/2010	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Condi02AR

Study information

Scientific Title

Randomised, blind and placebo-controlled trial for the CIGB-300 perilesional application in two dose levels in the recurrent and non recurrent genital condyloma

Study objectives
Treatment is considered successful if the difference in the response in the reduction of the affected area is above 30% for any of the doses compared to placebo

Ethics approval required
Old ethics approval format

Ethics approval(s)
Independent Ethics Committee for Trials in Clinical Pharmacology (Comité Independiente de Etica para Ensayos en Farmacología Clínica) approved on the 13th of April 2009

Study design
Prospective randomised multicentre blinded study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Recurrent and non-recurrent genital condyloma

Interventions
Patients will be randomised to 1 of 3 treatment arms
1. Placebo
2. CIGB-300 - 5 mg
3. CIGB-300 - 15 mg

A two week screening visit will take place to assess patient eligibility, at least 2 to 5 target lesions (area of the lesion between 20 to 80 mm2), should be identified. Patients included in the study will be randomly assigned to one of three study arms. Treatment consists of 3 perilesional applications at the base of the target lesion every 48 hours with a window of ±24hs.
After each application the potential local and systemic adverse events will be identified and monitored.
After the last application is made, weekly clinical evaluations for 3 weeks and then every two weeks, until week 12 will take place. At this time, clinical assessment of efficacy will be carried out that will define the response to treatment.
After this visit, patients will be followed every 3 months until one year after the last treatment

has been completed to confirm response and long-term security of the CIGB-300 application. At screening, at 2 and 8 weeks as well as at 6 and 12 months post-treatment blood studies will be conducted to assess the safety from the systemic point of view.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
1. Assess the safety of the perilesional application of CIGB-300 for the treatment of recurrent and non-recurrent condylomatous lesions
2. To assess CIGB-300 effect in the resolution of recurrent and non-recurrent, when considering the reduction in the number of lesions, lesion total area and the occurrence of recurrence of episodes

Secondary outcome measures
1. To assess the effect of CIGB-300 perilesional application in the reduction in number and area of genital warts lesions treated directly
2. To determine the locoregional effect of the product under study by assessing the area and number of genital warts not directly treated
3. To evaluate the possible effect of the product to avoid recurrence of the lesions resolved during treatment, assessed post-treatment
4. Define the optimal dose, in comparison with placebo
5. Identify, assess and report adverse events that occur during treatment in each treatment group so to identify the safest and most effective dose

Overall study start date
17/06/2010

Completion date
30/06/2012

Eligibility

Key inclusion criteria
1. Informed consent signed by the patient
2. Women with clinical diagnosis of recurrent and non recurrent genital condyloma
3. Presence of a condylomatous lesion or area of external confluent condylomatous lesions of not less than 20 or more than 80 mm2
4. The number of warts should be between 2 and 20
5. External genital warts or in perigenital regions
6. Negative pregnancy test
7. Age between 21 and 65 years inclusive

Participant type(s)
Patient

Age group

Not Specified

Sex
Not Specified

Target number of participants
132

Key exclusion criteria
1. Having received surgery treatment, ablative or immunomodulator treatment during the 30 days prior to inclusion
2. Presence of genital warts only located in the cervix, vagina, bladder or rectum
3. Pregnancy and lactation
4. Patients of childbearing age who are not using an adequate contraception method during treatment to prevent pregnancy. 5. Inadequately controlled chronic diseases (hypertension, diabetes, chronic kidney failure, heart failure, hyperthyroidism, malignant neoplasms, epilepsy, severe mental depression)
6. Patients with previous diagnosis of bleeding disorders and other chronic blood disorders (von Willebrand disease, haemophilia, leukaemia) or use of anticoagulants within 30 days before the study
7. Current genital herpes, which requires application of topical antivirals
8. Immunosuppressive disease, current intake of immunosuppressive/ immunomodulatory drugs within 30 days before the study.
9. Autoimmune Diseases (Lupus Erythematosus, Rheumatoid Arthritis, Multiple Sclerosis, Diabetes)
10. Severe allergy history as urticaria, dermatitis or persistent bronchitis and bronchial asthma
11. Febrile illness (temperature greater than 38°C) at the time or within 24 hours prior to administration of the product or suspected acute infectious disease by clinical examination
12. Diseases that compromise the patient's consciousness or the ability to give informed consent or to collaborate in the study
13. Concomitant skin lesions that prevent the administration of condylomatous lesions at the proposed site
14. Participating in another clinical trial

Date of first enrolment
17/06/2010

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
Argentina

Uruguay

Study participating centre

Sanabria 2353 1st floor
Buenos Aires
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Sponsor information

Organisation
Laboratorio Elea SACIFyA (Argentina)

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Sponsor type
Industry

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https://ror.org/032wae568

Funder(s)

Funder type
Industry

Funder Name
Laboratorio Elea SACIFyA (Argentina)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration