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Evaluation of GNR034 cream versus lactic acid cream to compare the effectiveness and safety in treating women diagnosed with a vaginal yeast infection

Submission date
16/11/2021

Recruitment status
No longer recruiting

Registration date
08/12/2021

Overall study status
Completed

Last Edited
26/11/2021

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Vaginal yeast infection is also known as vaginal candidiasis or genital candidiasis, or vulvovaginal candidiasis (VVC). It is an infection involving a type of fungus, or yeast. The fungus that is most commonly associated with a vaginal yeast infection is called Candida albicans. This fungus is responsible for up to 92% of all cases, with the remainder due to other species of Candida. These fungi can be found all over the body. They are normally present in warm and moist areas of the body. Some past studies have shown that between 20% to 50% of all women are normally carrying yeast in the vagina. Thus they do not have any symptoms. It seems that problems occur when Candida albicans in the vagina multiplies to the point of infection. Such an infection can cause vaginal inflammation, irritation, odour, discharge, and itching. C. albicans is kept from growing out of control by other types of bacteria that live naturally in the vagina. If the balance of these microorganisms becomes upset, C. albicans may be allowed to grow uncontrollably and lead to symptoms. The use of certain medications like antibiotics, changes in hormone levels, or certain diseases are examples of factors that can allow a vaginal yeast infection to develop. Vaginal yeast infections are very common. Almost 75% of women develop a yeast infection during their lives. A vaginal yeast infection is not considered a sexually-transmitted disease (STD). However, 12% to 15% of men develop symptoms such as itching and penile rash after sexual contact with an infected partner. Under normal circumstances, a vaginal yeast infection is not serious and can be treated with medications. In very rare cases, a yeast infection can lead to systemic Candida disease, which is fatal in 75% of people who develop this major complication. This occurs when the infection spreads throughout the body via the bloodstream. Women with weakened immune systems are most susceptible to this type of complication. The aim of this study is to evaluate the safety and effectiveness of GNR034 (Ginuril® cream) versus lactic acid administered by the vaginal route in women affected by a vaginal yeast infection and who are starting treatment with clotrimazole vaginal tablets.

Who can participate?
Caucasian women between 18 and 50 years of age with vaginal infections

What does the study involve?
Participants are randomly allocated to administer either GNR034 (Ginuril® cream) or lactic acid once per day for 7 consecutive days by the vaginal route according to the approved leaflet. Participants attended three visits: at the start of the study (Visit 1), Visit 2 after 3 days of treatment, and an end of study visit (Visit 3), 7 days after starting treatment.

What are the possible benefits and risks of participating?
The benefits of participation in this study are a free diagnosis and medical check and free treatment for vaginal infection. There were no side effects reported of the use of Ginuril during preclinical studies.

Where is the study run from?
Novintethical Pharma SA (Switzerland)

When is the study starting and how long is it expected to run for?
May 2015 to June 2016

Who is funding the study?
Novintethical Pharma SA (Switzerland)

Who is the main contact?
Alina Iordache
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Contact information

Type(s)
Scientific

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Clinical Trials Information System (CTIS)
2014-005315-16

Protocol serial number
CNG2711-14

Study information

Scientific Title
A double-blind, parallel, randomized, multicenter study to evaluate the safety and efficacy of NR034 (Ginuril®) versus lactic acid administered as co-adjuvant by vaginal route in women affected by a vaginal yeast infection and who are initiating treatment with clotrimazole vaginal tablets

Acronym
AVANTAGE

Study objectives
This was a double-blind, parallel, randomized, multicenter study to evaluate the safety and efficacy of GNR034 (Ginuril®) versus lactic acid administered as coadjuvant by vaginal route in women affected by a vaginal yeast infection and who are initiating treatment with clotrimazole vaginal tablets.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/05/2015, National Agency of Medicine and Medical Devices of Romania (Stefan Cel Mare 19-21 Road, District 2, Bucharest, Romania; +40 (0)212102880; comisia.bioetica@adsm.ro), ref: 2DM/22.05.2015

Primary study design
Interventional

Study design
Double-blind parallel randomized multicenter study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vaginal infection

Interventions
The participants are assigned randomly to a study treatment based on a computer randomized 1:1 scheme which generates the code of the treatment that is allocated to the specific patient. Participants are instructed to administer product A or B once per day for 7 consecutive days. The treatments (Product A or Product B) are administered by the vaginal route according to the approved leaflet. One group receives GNR034 (Ginuril® cream) and the other group lactic acid.

Patients attend three visits:
1. Baseline visit (Visit 1)
2. Visit 2 after 3 days of treatment
3. End of study visit (Visit 3), 7 days after beginning treatment

Intervention Type

Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
GNR034 (Ginuril®), lactic acid

Primary outcome(s)
1. Safety: occurrence and classification of adverse events (AE)/serious adverse events (SAE) /suspected unexpected serious adverse reactions (SUSAR), recorded using patient diaries on days 1, 3 and 7
2. Occurrence of undesirable systemic or local effects reported by the patient or observed by the physician during the whole study period, recorded on days 1, 3 and 7

Key secondary outcome(s)
Observed by self-report (patient diary) and by the physician during gynecological examinations:
1. Mycological count on days 1, 3 and 7 of treatment
2. Clinical symptoms:
2.1. Itching evaluated using the Scott-Huskisson scale on days 1, 2, 3, 4, 5, 6, 7
2.2. Leucorrhoea evaluated on days 1, 2, 3, 4, 5, 6, 7
2.3. Dysuria evaluated on days 1, 2, 3, 4, 5, 6, 7
2.4. Dyspareunia evaluated on days 1, 2, 3, 4, 5, 6, 7
3. Vaginal pH measured on days 1, 3, 7

Completion date
24/06/2016

Eligibility

Key inclusion criteria
1. Females between 18 and 50 years of age
2. Caucasian race
3. Suffering from vaginal yeast infection
4. Initiating therapy with clotrimazole vaginal tablets for 3 days
5. Signed informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit

50 Years

Sex
Female

Total final enrolment
42

Key exclusion criteria
1. Pregnant women or breastfeeding
2. Unwilling to sign the informed consent form
3. Allergy to one of the product ingredients

Date of first enrolment
11/11/2015

Date of final enrolment
17/06/2016

Locations

Countries of recruitment
Romania

Study participating centre
Cluj-Napoca - Clinical Emergency Hospital
ObGyn Department
Clinicilor Street 3-5
Cluj-Napoca
Romania
400000

Study participating centre
Bucharest "Saint John" Clinical Emergency Hospital
ObGyn Department
Vitan-Bârzești Street, 13
Bucharest
Romania
042122

Study participating centre
Unirea Medical Centre
Garii Boulevard, 3A

Brasov
Romania
500148

Study participating centre
Unirea Medical Centre
Calea Floreasca 14A
Bucharest
Romania
14452

Study participating centre
Saint Andrew Clinical Emergency Hospital
Brăilei Street 177
Galati
Romania
800578

Sponsor information

Organisation
Novintethical Pharma (Switzerland)

ROR
https://ror.org/05ypvb778

Funder(s)

Funder type
Industry

Funder Name
Novintethical Pharma SA

Results and Publications

Individual participant data (IPD) sharing plan

The data will be collected under the study confidentiality and for study purposes only, according to the approved informed consent form. The study data will be archived according to the sponsor requirements and local regulatory requirements.

IPD sharing plan summary

Not expected to be made available