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Randomised clinical trial comparing the efficacy between metronidazole and Shinus terebinthifolius Raddi (called aroeira) in vaginal use for the treatment of bacterial vaginosis

Submission date
18/06/2007

Recruitment status
No longer recruiting

Registration date
06/07/2007

Overall study status
Completed

Last Edited
01/09/2021

Condition category
Infections and Infestations

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomised clinical trial comparing the efficacy between metronidazole and Shinus terebinthifolius Raddi (called aroeira) in vaginal use for the treatment of bacterial vaginosis

Study objectives
Bacterial vaginosis is a polymicrobial clinical syndrome where the Lactobacillus are replaced by anaerobic bacteria, Gardnerela vaginalis and Mycoplasma hominis.

The study hypothesis is that metronidazole and aroeira have similar efficacy in the treatment of bacterial vaginosis, but aroeira has less impact in the vaginal flora, because it is a natural substance, extracted from a tree caulis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Commitee in Research of the Instituto Materno Infantil (c/o Prof Fernando Figueira) approved in March 2007.

Study design
Randomised double-blind controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Bacterial vaginosis

Interventions
The participants will be randomised into two groups of 150 women:
Control group: Metronidazole gel 0.75%, intravaginally, once a day for seven days.
Intervention group: Schinus terebinthifolius Raddi (aroeira) gel 3,996 ml/6 g, intravaginally, once a day for seven days.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Metronidazole, Shinus terebinthifolius Raddi (called aroeira)

Primary outcome measure
To compare the frequency of the clinical (Amsel Criteria) and bacteriological (Nugent criteria) cure assessed at baseline and after their next menses (approximately one month after therapy) between the two groups.

Secondary outcome measures
1. To compare the frequencies of the adverse effects of the two drugs
2. To compare the frequencies of the effects in the vaginal flora, observing the presence of lactobacillus in Papanicolaou smears at baseline and after their next menses (approximately one month after therapy)
3. To compare the frequencies of the effects of the two treatments by the presence of bacterias and fungi in vaginal cultures at baseline and after their next menses (approximately one month after therapy)

Overall study start date
20/06/2007

Completion date
20/06/2008

Eligibility

Key inclusion criteria
1. Women aged between 18 and 40 years
2. Women with vaginal discharge caused by bacterial vaginosis, diagnosed using the Amsel (clinical) and Nugent (Gram stein) criteria

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
300 women

Total final enrolment
277

Key exclusion criteria
1. Pregnant women
2. Women using antibiotics for other infections in the last 30 days
3. Women using any other vaginal treatment in the last 30 days
4. Women who have never had sexual intercourse
5. Women with other vaginal infections such as candidiasis or trichomoniasis
6. Women with a suggestive diagnosis of pelvic inflammatory disease

Date of first enrolment
20/06/2007

Date of final enrolment
20/06/2008

Locations

Countries of recruitment
Brazil

Study participating centre
Universidade Federal de Pernambuco
Recife
Brazil
50670-421

Sponsor information

Organisation
Institute for Maternal/Infant Health (IMIP) (Brazil)

Sponsor details
Rua dos Coelhos
300 - Boa Vista
Recife
Brazil
50070-550

Sponsor type
Hospital/treatment centre

Website
http://www.imip.org.br/

ROR
https://ror.org/01rtyyz33

Funder(s)

Funder type
Industry

Funder Name
The vaginal treatments will be provided by Laboratório Hebron (www.hebron.com.br) (Brazil). The assessments will be carried out at the Instituto Materno Infantil (Brazil) - c/o Prof Fernando Figueira, where the study will take place.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/01/2011	01/09/2021	Yes	No