

A prospective, placebo-controlled, double-blind study for the investigation of the effect and safety of EcoVag® as adjuvant treatment after treatment with clindamycin against bacterial vaginosis

Submission date

28/03/2007

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

24/04/2007

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

05/01/2021

Condition category

Infections and Infestations

☐ 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

LA-BV 2003 01

Study information

Scientific Title

A prospective, placebo-controlled, double-blind study for the investigation of the effect and safety of EcoVag® as adjuvant treatment after treatment with clindamycin against bacterial vaginosis

Study objectives

To assess if adjuvant treatment with EcoVag could increase initial healing and reduce the relapse of bacterial vaginosis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from The National Committees for Research Ethics in Norway (REK soer) on the 4th November 2003.

Study design

A prospective, randomized, placebo-controlled, double-blind 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

Intervention group:

Clindamycin (7 days) and EcoVag for four menstrual periods. EcoVag was administered for 5 to 10 days in the first menstrual period and for 10 days during each of the subsequent 3 periods.

Control group:

Clindamycin (7 days) and placebo for four menstrual periods. Placebo was administered for 5 to 10 days in the first menstrual period and for 10 days during each of the subsequent 3 periods.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

EcoVag

Primary outcome measure

Time from healing to relapse of symptoms, measured after one month, three and six months after treatment.

Secondary outcome measures

Number of patients initially healed, measured after one month, three and six months after treatment.

Overall study start date

02/02/2004

Completion date

02/02/2006

Eligibility**Key inclusion criteria**

Non-pregnant female between 18 and 60 years of age with regular menstrual period fulfilling Amsel criteria for bacterial vaginosis

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

100

Total final enrolment

100

Key exclusion criteria

1. Ongoing infection with candida albicans or clamidia trachomatis
2. Participating in another drug study within the last 6 weeks

Date of first enrolment

02/02/2004

Date of final enrolment

02/02/2006

Locations

Countries of recruitment

Denmark

Norway

Study participating centre

Solhoej 13

Nivå

Denmark

2990

Sponsor information

Organisation

Bifodan A/S (Denmark)

Sponsor details

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Hundested

Denmark

DK-3390

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erb@bifodan.dk

Sponsor type

Industry

ROR

<https://ror.org/05bzbnj80>

Funder(s)

Funder type

Industry

Funder Name

Bifodan A/S (Denmark)

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	results	15/01/2008	04/01/2021	Yes	No