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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	Recruitment status	[_] Prospectively registered
28/03/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/04/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/01/2021	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
Number of patients initially healed, measured after one month, three and six months after treatment.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
100

Key exclusion criteria
1. Ongoing infection with candida albicans or clamydia 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)

ROR
https://ror.org/05bzbnj80

Funder(s)

Funder type
Industry

Funder Name
Bifodan A/S (Denmark)

Results and Publications

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