

A phase II, double-blind, randomised, placebo-controlled, multi-centre trial to assess the efficacy and safety of the 100 mg clindamycin hydrochloride vaginal insert in women diagnosed with bacterial vaginosis

Submission date 15/11/2006	Recruitment status Stopped	☒ Prospectively registered
		☐ Protocol
Registration date 14/12/2006	Overall study status Stopped	☐ Statistical analysis plan
		☐ Results
Last Edited 14/09/2011	Condition category Urological and Genital Diseases	☐ Individual participant data
		☐ 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

Protocol serial number

Clin-Gyn-201

Study information

Scientific Title

Study objectives

It is anticipated that the Clindamycin Hydrochloride Vaginal Insert (CHVI) will provide therapeutic levels of clindamycin to the affected tissues over a sustained period.

Please note that this trial was cancelled (no sites were initiated, therefore no patients were dosed).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Thames Valley MREC on the 19/12/2006 (ref: 06/MRE12/84).

Primary study design

Interventional

Study design

Phase II double-blind, randomised, placebo-controlled, multi-centre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bacterial Vaginosis

Interventions

Day zero: screening assessment -

1. Written informed consent
2. Vaginal examination
3. Collect specimens for the diagnosis of BV
4. Diary card given to all subjects to complete

Method:

100 mg Clindamycin Hydrochloride Vaginal Insert to be self administered at home (dosing period approximately 24 hours)

Day eight: follow-up telephone call -

1. Subjects questioned regarding BV symptoms and any Adverse Events (AE)
2. Subjects will be instructed to contact the clinic at any time if they have any AE of concern or BV symptoms. The Investigator will decide if the subject should return to the clinic for assessment and treatment.

Day 26: follow-up visit -

1. Vaginal examination
2. Collect specimens for BV

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Clindamycin Hydrochloride

Primary outcome(s)

Therapeutic cure rate of BV

Key secondary outcome(s)

1. Clinical cure rate of BV
2. Improved cure rate of BV
3. Nugent score of BV
4. BV symptom resolution
5. Adverse events

Completion date

30/09/2007

Reason abandoned (if study stopped)

No sites were initiated, therefore no patients dosed.

Eligibility

Key inclusion criteria

1. Clinical diagnosis of Bacterial Vaginosis (BV), defined as having all four Amsel criteria
2. Gram stain slide Nugent score greater than or equal to four
3. No evidence of genital warts on vaginal and perineal examination
4. Provide written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

Key exclusion criteria

1. Known hypersensitivity to clindamycin or lincomycin
2. Diagnosis and received treatment for BV in the previous three months
3. Urinary tract infection in the previous six months
4. Diagnosis or treatment in the previous six months for Cervical Intra-epithelial Neoplasia (CIN)

or cervical carcinoma
5. Unavailable for the follow-up visit

Date of first enrolment
01/04/2007

Date of final enrolment
30/09/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Courtyard Clinic
London
United Kingdom
SW17 0QT

Sponsor information

Organisation
Controlled Therapeutics (Scotland) Ltd (UK)

ROR
<https://ror.org/03e9kb581>

Funder(s)

Funder type
Industry

Funder Name
Funded by Controlled Therapeutics (Scotland) Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration