ISRCTN33336878 https://doi.org/10.1186/ISRCTN33336878

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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 14/12/2006	**Overall study status** Stopped	
Last Edited 14/09/2011	**Condition category** Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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).

Study design
Phase II double-blind, randomised, placebo-controlled, multi-centre 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
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 measure
Therapeutic cure rate of BV

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

Overall study start date
01/04/2007

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

Age group
Not Specified

Sex
Female

Target number of participants
177

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
England

United Kingdom

Study participating centre
Courtyard Clinic
London
United Kingdom
SW17 0QT

Sponsor information

Organisation
Controlled Therapeutics (Scotland) Ltd (UK)

Sponsor details

1 Redwood Place
Peel Park Campus
East Kilbride
United Kingdom
G74 5PB

Sponsor type
Industry

Website
http://www.ctscotland.com

ROR
https://ror.org/03e9kb581

Funder(s)

Funder type
Industry

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

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