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A phase I, single-centre, open study to assess the pharmacokinetic profile and safety of a 100 mg Clindamycin Hydrochloride Vaginal Insert (CHVI) in healthy females

Submission date
17/09/2007

Recruitment status
No longer recruiting

Registration date
04/10/2007

Overall study status
Completed

Last Edited
12/11/2019

Condition category
Urological and Genital Diseases

[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Clin-Gyn-101

Study information

Scientific Title
A phase I, single-centre, open study to assess the pharmacokinetic profile and safety of a 100 mg Clindamycin Hydrochloride Vaginal Insert (CHVI) in healthy females

Acronym
CHVI

Study objectives
This study is to confirm the safety, tolerability and the pharmacokinetic profile of the hydrochloride forumation in healthy female volunteers. This treatment is expected to be effective in the treatment of patients diagnosed with bacterial vaginosis.

Hypothesis:
The concentrations of clindamycin (fee base) in plasma at pre-determined time-points.

Please note that as of 18/10/2007 the anticipated end date of this trial was extended from 09/10 /2007.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tayside Committee on Medical Research Ethics B, 21/08/2007, ref: 07/S1402/63

Study design
Phase I single-centre non-randomised non-controlled open study

Primary study design
Interventional

Secondary study design
Other

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
Pre-trial visit:
Prior to interventions, written informed consent will be gained. A screening assessment and a compliance check will be performed the day before dosing.

Day one:
Pre-dose checks, vitals, menstrual history check, a pre-dose pharmacokinetic (PK) sample and vaginal pH testing will be performed, and a check to see if the volunteer has any signs or symptoms of infection will also be performed.

After this, the study drug (100 mg Clindamycin Hydrochloride Vaginal Insert) will be administered (dosing period = 24 hours). Post insertion checks will include comfort questionnaires, PK blood samples, vitals and vaginal pH. The study drug will be removed at 24 hours and a urine sample for urinalysis will be taken.

Day two:
PK blood samples will be taken.

Days 3, 4, 5 and 6:
PK blood sample, vitals and urine sample for urinalysis information will be taken.

Adverse Events (AEs) and concomitant medication checks will be performed throughout the trial.

Post-trial visit:
Vitals, Electrocardiogram (ECG), safety bloods and urine samples, urine for pregnancy testing and a physical examination will be performed.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Clindamycin

Primary outcome measure
The concentrations of clindamycin (free base) in plasma at pre-determined time-points.

Secondary outcome measures
1. Assessments of all adverse events reported
2. Assessment of tolerability by review of completed comfort questionnaires
3. Assessment of vaginal pH at specified time-points
4. Measurements of residual amounts of clindamycin in used CHVI to calculate the remaining dose of clindamycin in order to determine the amount of drug released from the insert

Overall study start date
03/09/2007

Completion date
09/11/2007

Eligibility

Key inclusion criteria

1. Healthy female volunteers aged between 18 - 50 years
2. Urine negative for a urinary tract infection
3. Up to date with regular pap smear tests in accordance with local health authority guidelines
4. Agree to refrain from placing anything on the following list in their vagina other than the study drug from the day of admission to the clinical trial unit until completion of the follow-up visit:
4.1. Use of feminine deodorant sprays/products, spermicides*, douches, condoms*, tampons, diaphragms* or any other pharmaceutical or over the counter vaginal product
Barrier methods of contraception as indicated above (*) may be resumed following discharge from the clinic (Day 3)
4.2. Vaginal intercourse is permitted except for the 24-hour period prior to admission and during the residential period of the study
5. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Female

Target number of participants
10

Key exclusion criteria
1. Volunteers expected to menstruate from Day 0 to Day 6 or during the 48 hours prior to dosing
2. Volunteers who have a vaginal pH of 4.7 or higher and have any other signs or symptoms of infections at screening and prior to Dosing Day 1
3. Volunteers who have any significant history of drug allergies especially to clindamycin or lincomycin
4. Urinary tract infection in the previous 6 months or have a significant history of recurring urinary tract infections
5. Antimicrobial and/or antifungal therapy (systemic or intravaginal) within 14 days of dosing
6. Signs and/or symptoms of vaginal infection or infections within the last month or positive vaginal swab culture (to definite specific pathogens) at screening
7. Known current Sexually Transmitted Infection (STI) to be established by discussion
8. Contraindications for clindamycin per current labelling of marketed intravaginal formulations
9. Diagnosis or treatment in the previous 6 months for Cervical Intra-epithelial Neoplasia (CIN) or cervical carcinoma

Date of first enrolment
03/09/2007

Date of final enrolment
09/11/2007

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Drug Development Solutions Limited
Dundee
United Kingdom
DD1 9SY

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
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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		12/11/2019	12/11/2019	No	No