ISRCTN64808733 https://doi.org/10.1186/ISRCTN64808733

A randomised double-blind phase 1 study to assess the pharmacokinetics of C2F5, C2G12 and C4E10 when administered together in a gel vehicle as a vaginal microbicide

Submission date
23/10/2008

Registration date
26/01/2009

Last Edited
12/01/2015

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[X] 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

Protocol serial number
Mabgel1

Study information

Scientific Title

A randomised double-blind phase 1 study to assess the pharmacokinetics of C2F5, C2G12 and C4E10 when administered together in a gel vehicle as a vaginal microbicide

Acronym
MABGEL1

Study objectives
The investigational medicinal product used in this trial is designed to prevent infection with HIV. As this is a phase I study to investigate the pharmacokinetic properties of the product, the study endpoints will not include infection with HIV, and participants will be healthy volunteers.

Please note that as of 15/04/2013, the anticipated end date for this study was updated from 01 /01/2010 to 01/07/2010.

Study aim: To assess the pharmacokinetics of the specified monoclonal antibody (MAb) combination when applied vaginally.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 1 Research Ethics Committee, approval pending as of 23/10/2008 (ref: 08/HO304 /87)

Study design
Phase I double-blind randomised controlled single-centre trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
HIV

Interventions
The participants will be randomly allocated to the following three vehicles for vaginal administration of monoclonal antibodies C2F5, C2G12 and C4E10:

Arm 1: Mabgel (high dose)
Arm 2: Mabgel (low dose)
Arm 3: Placebo gel

For all arms, the duration of treatment is 12 days. Participants will be followed up for 4 to 5 weeks after their first dose (dependent on menstrual cycle).

Details of Co-Sponsor:
University of York
c/o Dr Sue Final

Research Support Office
University of York
York, YO10 5DD
United Kingdom
Email: smf3@york.ac.uk

Intervention Type
Drug

Phase
Phase I

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

Primary outcome(s)
Levels of MAbs in Weck-Cel vaginal secretions 1 and 8 hours post-1st dose and 1 and 8 hours post-12th dose.

Key secondary outcome(s))
1. 8 hour post-1st dose and 8 hour post-12th dose cervico-vaginal lavage MAb levels
2. 8 hour post-1st dose and 8 hour post-12th dose MAb levels in self-sampled vaginal aspirate
3. 8 hour post-1st dose and 1 hour post-12th dose plasma MAb levels
4. Number of grade 3 or above genital adverse events during the dosing or follow-up period
5. Number of grade 3 or above other clinical or laboratory adverse events confirmed at examination or on repeat testing respectively during the dosing or follow-up period
6. Number of events attributable to the study gel leading to discontinuation of gel

Completion date
01/07/2010

Eligibility

Key inclusion criteria
1. Females
2. Aged >=18 and <=45 years
3. In good health as determined by medical history, physical examination and clinical judgement
4. Willing and able to give written informed consent
5. Available for the duration of the study
6. Willing to undergo screening for HIV, hepatitis B & C, and sexually transmitted infections
7. Willing to abstain from vaginal practices including receptive oral sex and sexual intercourse from 48 hours before the first dose of the study gel until after visit 5
8. If physiologically fertile, using a reliable method of contraception for the two to three menstrual cycles covering the pre-study, and study dosing periods (methods defined as one of: consistent use of condoms with every act of sexual intercourse; combined oral contraceptive pill; intra-uterine contraceptive device; injectable contraceptive; progesterone implant)
9. Willing to abstain from using any genital preparations, other than the study gel, during the period of gel administration until after visit 5
10. Willing to abstain from using tampons during the period of gel administration until after visit 5
11. Judged by clinician to be able, and likely, to comply with the procedures required as set out

in the protocol
12. Have been registered with a GP for at least the past 3 months
13. Have access to a domestic refrigerator at home for the purposes of storing the study gel

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Untreated syphilis, gonorrhoea, trichomonas, chlamydia, Candida or bacterial vaginosis
2. Clinically significant (out of the normal range and deemed clinically significant by the Chief Investigator [CI]) haematological, biochemical, or coagulation assay abnormalities on screening
3. HIV infection, anti-HCV antibody positive, HbsAg positive
4. Abnormal findings on pelvic examination, deemed clinically significant by the CI
5. History of coagulation disorders
6. Significant current general medical illness
7. Irregular menstrual bleeding likely to cause vaginal bleeding during the dosing period as judged by the CI
8. Current participation, or participation within the last 2 months in another clinical trial
9. Treatment for cervical intraepithelial neoplasia (CIN) or other gynaecological instrumentation of the cervix within the past 3 months
10. Pregnant, within 12 weeks postpartum, or breast feeding
11. Unlikely to comply with protocol
12. Have any condition which, in the opinion of the investigator, might interfere with the evaluation of the study objectives
13. Unable to fluently read and speak English to a level adequate for the full comprehension of procedures required in participation and consent

Date of first enrolment
01/04/2009

Date of final enrolment
01/07/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
York HIV Research Group
York
United Kingdom
YO31 7WE

Sponsor information

Organisation
York Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/027e4g787

Funder(s)

Funder type
Other

Funder Name
European Commission (Belgium)

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/12/2014		Yes	No