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A phase II, double blind, placebo controlled, randomised, single centre study to assess the safety, tolerability and acceptability of Dextrin-2 Sulphate gel in sexually active female subjects and their male sexual partners at low risk of Human Immunodeficiency Virus (HIV) infection

Submission date
03/10/2000

Recruitment status
No longer recruiting

Registration date
03/10/2000

Overall study status
Completed

Last Edited
30/07/2009

Condition category
Infections and Infestations

[_] 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
E164/40

Study information

Scientific Title

Acronym
SHIELD

Study objectives
This phase II trial will investigate the safety and acceptability of 0.125% Dextrin Sulphate in healthy sexually active females.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
HIV, Acquired Immunodeficiency Syndrome (AIDS)

Interventions
Female subjects will be randomised to receive Dextrin Sulphate or placebo gel

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
0.125% Dextrin Sulphate

Primary outcome measure
Genital epithelium disruption and systematic absorption

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/1998

Completion date
30/04/2000

Eligibility

Key inclusion criteria
Female subjects inclusion:
1. Healthy sexually active women, aged between 18 and 45 years, with a regular male partner
2. Using a combined oral contraceptive pill (first pill within last two or next two days)
3. Willing to undergo a sexually transmitted disease (STD) screen
4. Willing to complete a daily diary
5. Willing to abstain from using any genital preparations, other than the study gel
6. Willing to abstain from using any aspirin-related drugs (NSAIDs) eg 'Neurofen', 'Anadin'
7. Written informed consent given
8. Male partner willing to use condoms for every episode of sexual intercourse.
For those whose male partner wishes to participate in Part 2 of the study, an HIV antibody test will be required at visit 3.

Male subjects inclusion:
1. Healthy man aged 18 years or more
2. Willing to undergo STD screen
3. Willing to complete daily diary
4. Willing to abstain from using any genital preparations
5. Willing to have an HIV antibody test
6. Given written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
117

Key exclusion criteria
Female subjects exclusion:
1. Pregnancy
2. Breastfeeding
3. Within 12 weeks postpartum
4. Within 12 weeks of treatment of cervical intra-epithelial neoplasia (CIN)
5. Current use of an intravaginal preparation (e.g. tampons)
6. Past history of genital ulcerative disease
7. Current antibiotic or anticoagulant therapy
8. Chemotherapy or immunotherapy within the past three months
9. Known intolerance to heparin, dextrin sulphate or other anticoagulants
10. Current discomfort or pain during sexual intercourse
11. Post-coital bleeding in the past three months
12. Known HIV positive
13. Currently participating in another trial
14. Considered unsuitable for trial

Male subjects exclusion:
1. Past history of genital ulcerative disease
2. Current antibiotic or anticoagulant therapy
3. Chemotherapy or immunotherapy within the past three months
4. Known intolerance to heparin, dextrin sulphate or other anticoagulants
5. Current discomfort or pain during sexual intercourse
6. Known HIV positive
7. Currently participating in another trial
8. Considered unsuitable for the trial

Date of first enrolment
01/12/1998

Date of final enrolment
30/04/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Research Fellow
London

United Kingdom
W2 1NY

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article	results	01/12/2002		Yes	No