

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	<input type="checkbox"/> Prospectively registered
Registration date 03/10/2000	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/07/2009	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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