

Barriers to recruitment in a phase II Microbicide clinical trial

Data from a safety trial of Dextrin 2
Sulphate intra-vaginal gel in urban
Uganda

Objectives

- to determine the safety of Dextrin 2 Sulphate (DS) gel in terms of local and systemic adverse events
- to determine the acceptability of the study gel

Trial design

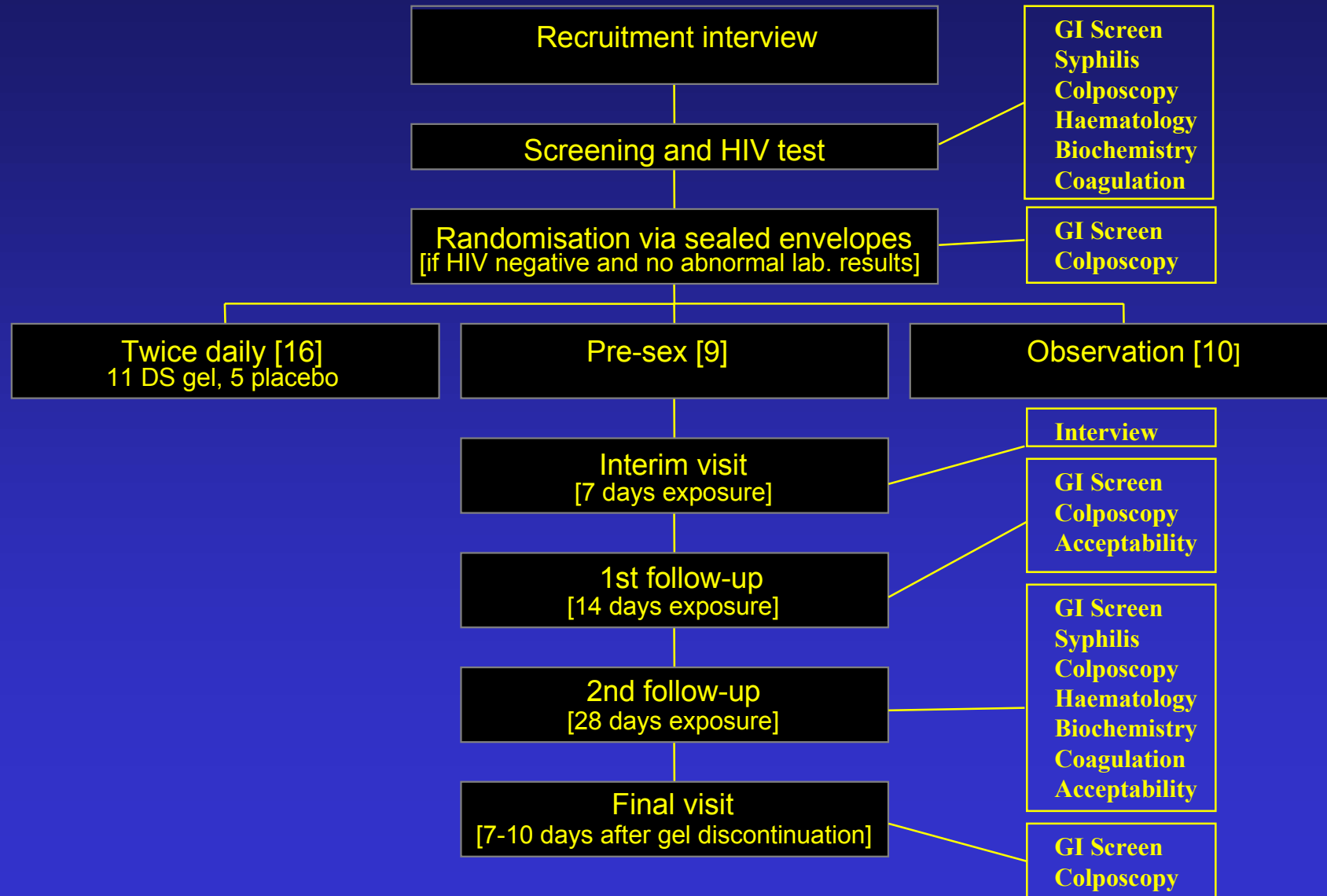
Design

- Phase II randomised, double blind placebo-controlled safety trial

Population

- sexually active women recruited from the post-natal clinic of Nsambya hospital in Kampala or outreach clinics in the surrounding area.

MIA-001 study design



Anticipated barriers - inclusion/exclusion criteria

- HIV testing
 - Willing to undergo an HIV test
- Consistent condom use policy
 - Willing to accept health education about condoms and to be supplied with condoms to be used at every episode of sexual intercourse during the study

Recruitment visit

- Recruitment interviews at post-natal and outreach clinics conducted by social scientist, nurse or doctor
- Verbal explanation of trial to women - background, purpose, inclusion and exclusion criteria of the trial
- Mandatory HIV testing & consistent condom use
- Information sheet in English or Luganda given to participant to take home
- Refund of expenses for the participants discussed
- Interested women encouraged to discuss participation with partner

Study population

- 15 to 20 women approached each week over a 4 month period resulting in 103 women booking screening visits

Main reasons for not booking screening visits

- trial's policy of consistent condom use
- assumed opinion of the woman's partner
- having blood taken

No women were put off by the thought of an HIV test - objection to venepuncture.

Screening

- 61 women attended a screening visit
- ~41% of those booking a screening visit did not attend

Those not attending were followed up - most gave 1 of 2 reasons for not attending:

- not enough time to keep returning to the site for study visits
- her partner had disapproved of her participation in the trial

Partner disapproval

- Condom compliance
 - condom use would not be tolerated in the relationship: sexual pleasure, infidelity
 - man should control the condoms
- Gel use
 - use of the gel would free women of the burden of contracting HIV and hence promote promiscuity
- No disapproval based on involvement in medical research related to HIV/STIs

HIV testing

| | |
|--|-----------------------------|
| Total screened | 61 |
| Registered at hospital HIV clinic | 6 |
| Pre-test counselling received | 55 |
| Capillus rapid HIV test results | 16 positive out of 55 tests |
| Serology results | 14 positive out of 52 tests |
| Discordant results (Capillus v. Elisa) | 1 Capillus +, Elisa – |
| Total originally preferring not to know their results | 2 |
| Participants deciding not to receive results after 2 weeks | 0 |
| Total new positives choosing to immediately disclose to their spouse | 4/14 |
| Total new positives accepting immediate referral to HIV clinic | 8/14 |
| Total not receiving results | 0 |

Conclusions on HIV testing

- Potential participants were more likely to be put off by the thought of venepuncture than by the HIV test itself
- After 2 decades of the HIV epidemic and numerous behaviour and educative interventions, there is little stigmatisation associated with HIV testing and positive results in this study population
- HIV testing is not a barrier to participation in this trial.

Conclusions on condom policy

- Relationship issues acted as a barrier to recruitment
 - issues such as infidelity and control prevented women booking screening visits, and if they did book them prevented them from attending.
- A requirement for consistent condom use was a barrier to recruitment for a proportion of the potential population.

Implications

- For the next stage of the phase II trial
 - information sheets designed for male partners
 - male partners of HIV positive women invited to study site
 - logistical implications of inviting all men to site
- For phase III trials
 - women looking to men for approval so study staff should as well
 - involving partners may be crucial in gaining acceptability for product

Trial staff & institutions involved

- Principal investigators
Prof. J. Whitworth, Dr. P. Okong, Dr. R. Byaruhanga, Dr. C. Lacey
- Trial team
Dr. M. Bukenya, J. Pickering, S. Namukwaya, G. Kintu
- Laboratory managers
P. Hughes & Sister Jude Namatovu
- Institutions
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Medical Research Council Programme on AIDS in Uganda
Imperial College Clinical Trials Unit, London, UK
- DS gel supplied by
ML Laboratories PLC, UK