

RANDOMIZED CONTROLLED TRIALS ON VAGINAL MICROBICIDES IN CAMEROON: SITE INTRODUCTION AND LESSONS FROM PAST EXPERIENCE

**Microbicides 2002
12-15 May 2002
Antwerpen, Belgium**

By Leopold ZEKENG

☞ Head of Laboratoire de Santé Hygiène Mobile, Ministry of Health

☞ Former in-country trials PI

BACKGROUND

- **2 RCT on Nonoxynol-9 carried out between 1996 – 2000**
- **70mg film and 100mg gel formulation**
- **Female Sex Workers and Women at risk for STIs**
- **Non-spermicide lubricated male latex condoms**
- **GCP and GLP**

OBJECTIVE

To assess the effectiveness of different formulation of Nonoxynol-9 in preventing male to female transmission of STIs including HIV.

Design and Methodology

| | | |
|-------------------|---|---|
| TITLE | ➤ Conceptrol gel and STD | ➤ HIV and Nonoxynol-9 |
| DESIGN | ➤ 2 arms, Open label | ➤ 2 arms, Double-blind |
| PRODUCT | ➤ 100mg of N-9 (4%) in 3,5 ml gel | ➤ 70mg of N-9 (28%) in 5x5 cm film. |
| ENDPOINTS | ➤ GC, CT, HIV | ➤ HIV, GC, CT |
| DURATION | ❖ 6 months FU | ❖ At least 12 months FU |
| POPULATION | ❖ Uninfected Women (18-35yrs) at risk of acquiring STIs | ❖ Uninfected FSW (18-45yrs) at risk for acquiring STIs. |
| | ❖ Willing to use study product or placebo and to know their HIV-test result | |

| | | |
|------------------|--|-----------------------|
| Size | ➤ 1,200 subjects | ➤ 1,292 subjects |
| Sites | ➤ 1 | ➤ 3 |
| SCREENING | <ul style="list-style-type: none"> ❖ Written consent. ❖ Negative participants enrolled. ❖ Participants with curable STD are given free treatment. ❖ HIV positive women are referred for psychosocial support | |
| FOLLOW UP | ➤ Pharmacies monthly | ➤ Main Clinic monthly |
| | ➤ Participants counselled, interviewed, tested for GC, CT and HIV | |

ACHIEVEMENTS

- Capacity building on CT under GCP/GLP labels
- CT possible in Africa by Africans
- Infrastructure re-enforcement
- FSW peer educators trained
- Part of Microbicides Networking Groups
- Competent staff to conduct clinical trials on Microbicides

CHALLENGES AND SOLUTIONS

| PHASES | CHALLENGES | SOLUTIONS |
|-------------------------|---|--|
| PLANNING | <ul style="list-style-type: none">➤ Health authorities misgivings | <ul style="list-style-type: none">➤ Advocacy➤ Early Involvement |
| INFORMED CONSENT | <ul style="list-style-type: none">➤ Written informed consent. | <ul style="list-style-type: none">➤ Increase patients awareness and the protection of their rights➤ Part of GCP➤ Witness if not educated |

RECRUITMENT

➤ Inaccurate information on study process and aims

➤ Voluntary participation

➤ Handling participants flow

➤ Refer eligible participant to study staff for accurate information

➤ Proper training of staff

➤ Awareness of their rights

➤ Access to care in health centers if not enrolled in the study.

➤ Start small and scale up.

RECRUITMENT

➤ Discontent of women with STIs negative results

➤ Education,
➤ Boost their self-esteem of being STIs free

➤ Perception of being use as "Guinea pigs"

➤ Product has been on market for many years
➤ Studies done in other countries
➤ Different HIV Epidemiological pattern

➤ Access to non sex workers population at risk.

➤ Health centers for recruitment

➤ HIV testing and result confidentiality

➤ Pre and post counseling
➤ Code used on sample

ENROLMENT

➤ Lack of interest after screening

➤ Rigorous selection when recruiting

➤ Negative rumours.

➤ Study approved Health authorities, and different ethical committees

➤ Fear of knowing HIV test results.

➤ Good counseling
➤ Psychological support
➤ Connect with PLA associations

➤ Being randomized in the "control group"

➤ Doubts on product's protection

**FOLLOW
UP**

➤ Tracing back participants

- Know participant house from enrolment
- Supervision staff exclusively female
- Inform participant on supervision visit
- At least one supervision visit per week
- Pain killers, anti- malaria, etc. given free.
- Quality of care provided by staff.
- Daily report of absenteeism
- Follow up forms and exams easy to perform by well trained staff
- Physician available for 'Adhoc visit'
- Proximity to follow-up sites

➤ Women hiding their participation to parents and partner

- Participant informed on supervision visit

In conclusion:

- Many Challenges in conducting clinical trials
- Training, imagination and the capacity to anticipate some problems are essential