

Acceptability of the Study Gel Among COL-1492 Study Participants

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on behalf of the COL-1492 study group

Randomised placebo-controlled triple blind trial among HIV(-) sex workers

- COL-1492 vs. placebo gel
- Primary objective
Effectiveness in preventing male-to-female vaginal HIV transmission
- Secondary objectives :
STD protection; Safety; Acceptability

COL-1492 Collaborators

SPONSORS: UNAIDS: J. Perriens COLUMBIA Labs: H. Levine

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DATA MANAGEMENT & ANALYSIS: B. Mâsse, L. Ross, R. Bois, E. Demers

SECONDARY ANALYSIS: E. Goetghebeur, A. Vandebosch

MONITORS: Durban: Clindepharm (ph.II), K. Mlisana (ph.II)

Hat Yai: L. Bodhidatta (II),
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Cotonou: S. Kassim (II), N. Fonton (III)

Abidjan: J.M. N'Gbichi

Bangkok: L. Bodhidatta

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CENTRES PHASE III: Durban: S. Abdool Karim, G. Ramjee, N. Morar

Hat Yai: V. Chandeying

Cotonou: M. Alary, L. Mukenge, N. Géraldo

Abidjan: P. Ghys, M. Diallo, B. Vuylsteke, V. Ettiègne-Traoré

CENTRES PHASE II: Durban and Hat Yai

Bangkok: P. Sirivongrangson, S. Niruthisard

Johannesburg: H. Rees, C. Richards, P. Ndaba

And all the trial participants



Trial Procedures

- ▶ monthly clinic visits
- ▶ visits 1, 2, 5 more detailed acceptability questionnaire
- ▶ STD check up and treatment
- ▶ condom counselling and distribution
- ▶ HIV testing

Vaginal Acts With Gel And/or Condom Use by the Study Participants

	<u>Clients</u>	<u>Partners</u>
Estimated total no. of acts	469 439	61 180
Condom + gel %	70.9	38.2
Condom only %	17.4	6.8
Gel only %	9.0	32.0
Nothing %	2.7	23.0

Acceptability at visits 1-2-5 in phase III

	Placebo	COL-1492
Not liked % (V)	2.1	1.6
Easy to apply %	98.1	98.1
Affecting sex %	30.3	30.0
If affecting, improving %	93.4	92.0
Informed clients % (V)	37.1	40.7
Informed partners % (V)	38.6	45.4

Acceptability at visits 1-2-5 in phase III (cont.)

	<u>Not liked</u> <u>% (No. visits)</u>	<u>Easy to apply</u> <u>% (No. answers)</u>	<u>Would Continue</u> <u>% of visits</u>
Abidjan	4.5 (397)	98.2 (379)	87.7
Cotonou	1.3 (527)	99.8 (490)	91.5
Durban	0.2 (477)	98.8 (406)	81.8
Hat Yai	1.7 (293)	94.4 (288)	52.6
Total	1.8 (1694)	98.1 (1563)	81.1

Why did participants like the gel?

	Easier sex %	HIV-prevention %
Abidjan	41.6	5.1
Cotonou	49.0	22.5
Durban	2.2	53.6
Hat Yai	40.0	7.8
Total	33.3	23.3

Did the Gel Affect Sexual Intercourse?

	Affects sex %	If affects, improves %	Why: easier sex%
Abidjan	24.3	96.7	69.7
Cotonou	41.4	96.0	93.8
Durban	18.2	90.5	13.4
Hat Yai	35.8	84.5	80.0
Total	30.1	92.8	73.6

Did Participants Inform Clients/Partner?

	Clients %	Partners %
Abidjan	50.9	53.9
Cotonou	53.5	45.2
Durban	23.1	40.7
Hat Yai	21.8	21.8
Total	38.8	41.9

Trends in Reported Effects

	Age OR (p)	Painful Sex OR (p)
Abidjan	1.06 (0.017)	1.96 (NS)
Cotonou	1.02 (NS)	3.55 (0.003)
Durban	1.07 (0.005)	1.90 (0.049)
Hat Yai	0.99 (NS)	4.82 (0.031)

Conclusion

- Participants liked the gel, no differences between COL-1492 and the placebo gel
- The gel improved sexual intercourse in about 30 %
- There were differences between centers