ACCEPTABILITY OF EMERGENCY CONTRACEPTION (EC) IN ACTG A5375

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BACKGROUND

- Contraceptive requirements for participants capable of pregnancy can be a barrier to cisgender women's participation in clinical trials
- Expanding trials' listed contraceptive options to include EC *if indicated* could increase trial participation and enhance participant autonomy
- EC is key part of medical management of sexual assault, which is highly prevalent among women living with HIV
- ACTG A5375 (clinicaltrials.gov NCT03819114; Scarsi KK, et al *Contraception* 2023) studied the PK and safety of dose-adjusted levonorgestrel (LNG) EC combined with efavirenz-based ART or rifampicin-containing TB therapy, with a secondary objective to **assess the acceptability and practicality of EC as a contraceptive option in ACTG trials**

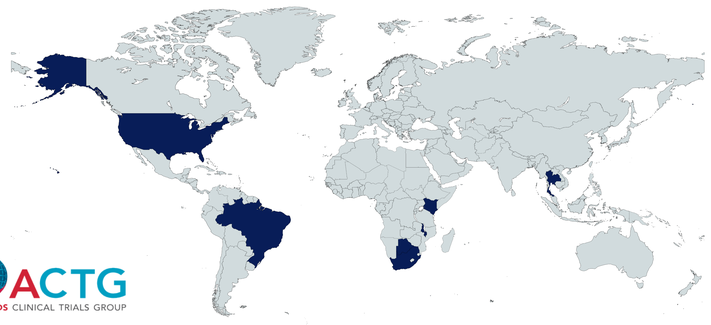
METHODS

- At study entry (Day 0), participants did not require EC for prevention of pregnancy, and received a single dose of LNG
- Interviewer-administered questionnaires assessed attitudes and experiences with EC, recent contraceptive use, and contraceptive preference during clinical trials participation
- Responses were summarized using descriptive statistics



RESULTS

- 122 cisgender women (median [IQR] 34 [27,41] years) were enrolled between May 2019- Nov. 2020 in Brazil, Botswana, Kenya, Malawi, South Africa, Thailand, USA
- The majority of participants were Black (66.4%), followed by Asian (27.0%); White (4.9%); and multiple races (0.8%); 9.0% were Latina.
- Most (79.5%) had **never** used LNG EC prior to study entry
- 22.1% reported complete abstinence within 120 days prior to entry



ACTG AIDS CLINICAL TRIALS GROUP

In ACTG A5375, levonorgestrel EC was an acceptable contraceptive option with the potential to address a barrier to clinical trial participation, particularly when two contraceptive methods are required and for participants not regularly having sex that could lead to pregnancy.

EC has additional implications for promoting survivor autonomy during the provision of comprehensive sexual assault services for women with HIV.

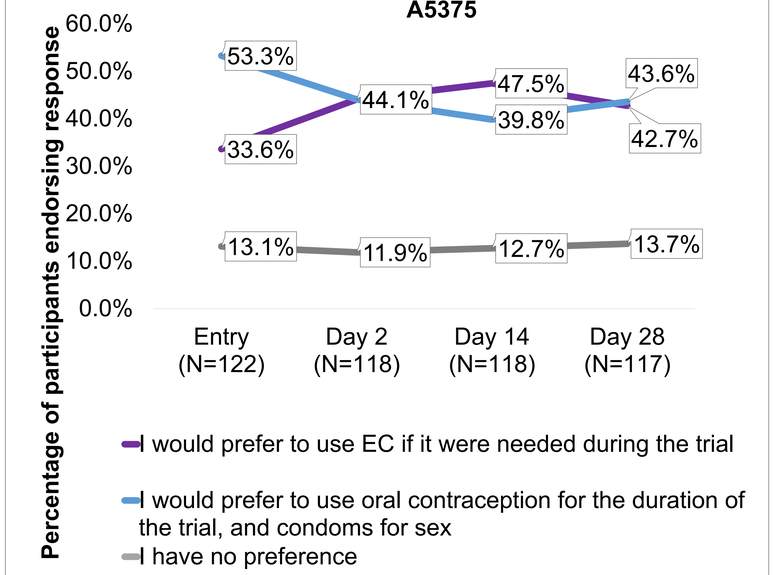
- Participants reporting that EC would increase willingness to participate in a trial was high at entry and increased at Day 28 (**Table**).
- In abstinent participants, this proportion remained stable from Day 0 to 28 (66.6%).

Question: Imagine there were a clinical trial that you were both interested in and qualified for, and LNG emergency contraception were an acceptable contraceptive option for those who do not regularly have sex that could lead to pregnancy. What impact would this requirement have on your participation in that clinical trial?

	Day 0 (n=122)	Day 2 (n=120)	Day 14 (n=119)	Day 28 (n=119)	Absolute change
I would be **less likely** to participate.	12 (9.8%)	11 (9.1%)	18 (15.1%)	13 (10.9%)	+1.1%
I would be **more likely** to participate.	78 (63.9%)	81 (67.5%)	80 (67.2%)	84 (70.6%)	+6.7%
It would have **no impact.**	19 (15.6%)	22 (18.3%)	19 (15.9%)	19 (15.9%)	+0.3%
I don't know.	13 (10.6%)	6 (5.0%)	2 (1.7%)	3 (2.5%)	-8.1%

- At entry, most (53.3%) preferred daily oral contraceptive pills (OCP) versus EC if needed (33.6%); **by Day 28, preferences for OCP versus EC had converged** (**Figure**).

Figure: Participant reported preference for EC versus OCP as contraceptive options during a trial in ACTG A5375



CONCLUSIONS

- EC was acceptable to participants at entry; acceptability increased after receiving a single dose of LNG during the trial, as did knowledge of where to access EC
- Adding EC as a contraceptive option in clinical trials could address a barrier to women's participation, particularly when two methods are required and for participants not regularly having sex that could lead to pregnancy.
- A trauma-informed approach to EC is essential considering the high prevalence of sexual assault and gender-based violence among women with HIV

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