Dolutegravir+Lamivudine vs Efavirenz Regimen in Adults With HIV-Tuberculosis: A Randomized Trial

Xiaoqin Le † [1], Wei Song [1], Lin Gu [1], Li Liu [1], Yanyun Dou [2], Ke Lan [2], Zhihao Meng [2], Yihong Zhou [3], Yanqiu Lu [3], Min Liu [3], Yaokai Chen [3], Min Jiao [4], Xuan Yang [4], Yan Sun [4], Congxia Wu [5], Zuoyu Huang [5], Meiyin Zou [5], Bo Tian [6], Jun Liu [6], Aichun Huang [7], Qisi Su [7], Zhiman Xie [7], Wenyao Tu [8], Jinhong He [8], Xiaoxin Xie [8], Yuhong Xiong [9], Aihua Deng [9], Jinchuan Shi [10], Jianhua Yu [10], Lianguo Ruan [11], Ke Hong [11], Tangkai Qi [1], Jianjun Sun [1], Zhenyan Wang [1], Yang Tang [1], Shuibao Xu [1], Junyang Yang [1], Youming Chen [1], Yueming Shao [1], Jiangrong Wang [1], Jun Chen [1], Renfang Zhang [1] and **Yinzhong Shen [1] ***

[1] Shanghai Public Health Clinical Center, Fudan University, Shanghai, China; [2] Chest Hospital of Guangxi Zhuang Autonomous Region, Liuzhou, China; [3] Chongqing Public Health Medical Center, Chongqing, China; [4] Henan Provincial Hospital of Infectious Diseases, Zhengzhou, China; [5] Nantong Third People's Hospital, Nantong, China; [6] Third People's Hospital of Kunming, Kunming, China; [7] Fourth People's Hospital of Nanning, Nanning, China; [8] Guiyang Public Health Clinical Center, Guiyang, China; [9] Jiangxi Chest Hospital, Nanchang, China; [10] Hangzhou Sixth People's Hospital, Hangzhou, China; [11] Wuhan Jinyintan Hospital, Wuhan, China

781

BACKGROUND

- The coinfection of HIV and mycobacterium tuberculosis (MTB) remains a major public health challenge in China.
- Complex drug–drug interactions and poor adherence, largely driven by high pill burden, contribute to low treatment success rates.
- Dual therapy with **dolutegravir plus lamivudine (DTG/3TC)**
  - recommended as a first-line option in people with HIV
  - has not been fully assessed in people with HIV and TB
- **Objective:** to evaluated efficacy and safety of **DTG/3TC** in HIV/TB coinfected individuals.

METHODS

- **Study design**: 1:1 randomized, prospective, parallel-controlled trail conducted in 11 hospitals from July 2023 to December 2025 in China (**ChiCTR2300075493**) .
- **ART regimen**:
  - ✓ **2DR arm** → DTG (50mg twice daily) + 3TC
  - ✓ **3DR arm** → EFV (600mg daily) + TDF + 3TC
- **Anti-TB**: rifampin-based anti-TB therapy≤ 2 weeks
- **Primary endpoints**: Viral suppression rate (HIV-1 RNA <50 copies/mL) in the modified intention-to-treat (mITT) set at Week 24. The study was not powered to compare arms.

mITT set: defined as receiving at least one dose of ART

- **Inclusion criteria:**
  - ✓ Age ≥18 years old
  - ✓ Newly diagnosed HIV-1 infection and ART-naïve
  - ✓ Newly diagnosed TB and Anti-TB therapy ≤2 weeks
  - ✓ **Excluding** those with rifampin or Antiretroviral drugs resistance, or coinfected with HBV, or severe hepatic or renal injury

Abbreviations: DTG – dolutegravir, 3TC – lamivudine, EFV – efavirenz, TDF – tenofovir disoproxil fumarate, ART – antiretroviral therapy, 2DR – two drug regimen, 3DR – three drug regimen, TB – tuberculosis, TB-IRIS – tuberculosis associated immune reconstitution inflammatory syndrome

Dual therapy — *Dolutegravir plus lamivudine* has good efficacy and safety in people coinfected with HIV and tuberculosis.

RESULTS

Baseline Characteristics

- Total 98 participants finished Week 24 follow-up.
- For 2DR arm (n=54), 48.1% of participants had baseline HIV-1 RNA ≥500,000 copies/mL, with a median CD4 count of 48 cells/μL.
- For 3DR arm (n=44), baseline HIV-1 RNA ≥500,000 copies/mL was in 34.1% of participants, with a median CD4 count of 45 cells/μL (Table 1).

Table 1. Baseline Characteristics of Participants in the Two Study Arms

	Total (n=98)	2DR arm (n=54)	3DR arm (n=44)	P value
Male, n (%)	88 (89.8)	47 (87)	41 (93.2)	0.5
Age, years	49±13	48±13	51±13	0.25
$\log_{10}$ (HIV RNA), copies/mL	5.5 (5.1-6.1)	5.7 (5.2-6.2)	5.4 (5.0-6.0)	0.86
Baseline HIV RNA ≥5×10^5copies/mL, n (%)	41 (41.8)	26 (48.1)	15 (34.1)	0.16
CD4 counts, cells/μL	47 (19-100)	48 (26-102)	45 (13-84)	0.44

Virologic Response Rate

- **The Weeks 24 response rate were 55.6% (95%CI:41.9, 69.2) for the 2DR arm and 50% (95%CI: 34.6, 65.4) for the 3DR arm** (Figure 1).

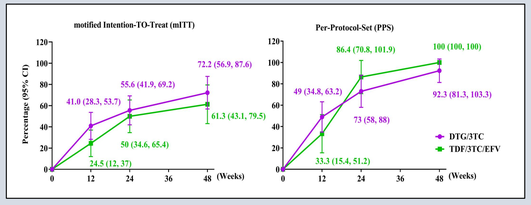


Figure 1. Virologic Response Rate at Weeks 12, 24, and 48

- Compared with 3DR arm, participants in the 2DR arm exhibited superior immunologic recovery (Figure 2) .

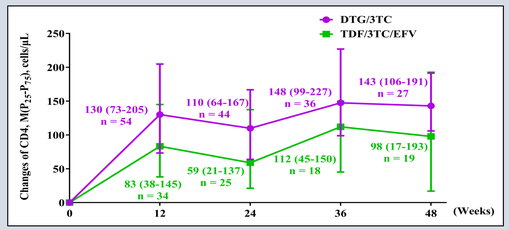


Figure 2. CD4 Changes from Baseline at Weeks 12, 24, and 48

Safety Outcomes

- A total of **58 adverse events** were reported (Figure 3).
- **TB-IRIS:** 14 events — 9 in 2DR, 5 in 3DR; no ART discontinuations due to IRIS.
- **Deaths**: 5 events — 1 in 2DR, 4 in 3DR; none related to ART.
- **Drug-induced hypersensitivity**: 5 discontinuations — 4 for EFV, 1 for DTG.
- **Protocol-defined virological failures**: 4 events — 2 in 2DR (1 with DTG resistance G118GR), 2 in 3DR (2 with EFV resistance).

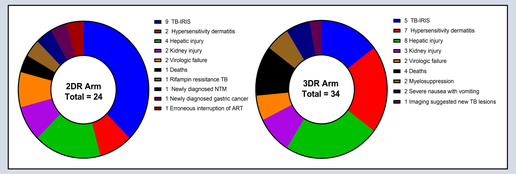


Figure 3. Adverse Events Reported in the 2DR and 3DR Arms

TB Treatment outcomes

- There were 69 evaluable TB treatment outcomes.
- TB treatment success rate were 78.9% *vs.* 67.7% in the 2DR and 3DR arms (Figure 4).

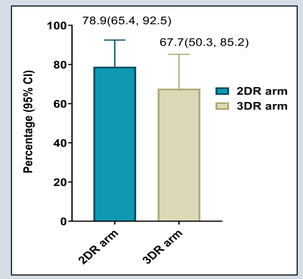


Figure 4. TB treatment success rate

CONCLUSIONS

- **Double-dose dolutegravir plus lamivudine was well tolerated and effective in adults with HIV/TB receiving rifampin-based therapy.**
- **This dual therapy may provide a new option for patients with HIV and TB**.

ACKNOWLEDGEMENTS

- Sincerely thank to all members of study team from 16 hospitals across China for their dedication and collaboration.
- Especially grateful to all study participants and their families for invaluable contributions and unwavering support.

FOUNDING

Science and Technology Commission of Shanghai Municipality (**NO. 21Y31900400**).

CONTACT INFORMATIONS

† **First author**: nephrole@163.com

* **Presenting author**: shenyinzhong@shphc.org.cn