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Two dolutegravir-based regimens as effective as efavirenz in people living with HIV starting antiretroviral therapy

The ADVANCE trial: Phase 3, randomised comparison of TAF/FTC-DTGT, TDF/FTC-DTGT or TDF/FTC/EFV for first-line treatment of HIV-1 infection

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BACKGROUND

- In low and middle income countries, most treatment-naïve people living with HIV (PLWH) take tenofovir disoproxil fumarate with emtricitabine (or lamivudine) with efavirenz (TDF/FTC/EFV).
- Dolutegravir (DTG) and tenofovir alafenamide fumarate (TAF) are recommended in international guidelines.
- Limited clinical experience with these ARTs in sub-Saharan Africa, over 50% of PLWH have pre-treatment DTG resistance.

METHODS

- We conducted a 96-week open label randomised trial in South Africa, comparing TAF/FTC/DTG, TDF/FTC-DTGT and TDF/FTC/EFV. N = 1053 ART-naïve PLWH.
- Inclusion criteria: age 18-24 years, no prior ART > 30 days, creatinine clearance > 60 mL/min (> 80 mL/min if < 19 years) and HIV-1 RNA > 500 copies/mL.
- Exclusion criteria: pregnancy or tuberculosis at screening or assessment visits.
- No screening for baseline resistance (as per South African treatment guidelines).
- Primary treatment failure endpoints: 48-week HIV-1 RNA > 50 copies/mL, discontinuation or missing data (TC was inferiority margin < 20%, significance level p < 0.017, adjusted for multiple comparisons).
- We report 48-week efficacy and safety data.



Table and Figures

Table 2: Baseline demographics

Characteristic	TAF/FTC-DTGT (n=351)	TDF/FTC-DTGT (n=351)	TDF/FTC/EFV (n=351)
Age (mean, SD)	22.1 (2.1)	22.1 (2.1)	22.1 (2.1)
Sex (n, %)			
Male	200 (57.0)	200 (57.0)	200 (57.0)
Female	151 (43.0)	151 (43.0)	151 (43.0)
Weight (mean, SD)	60.5 (12.5)	60.5 (12.5)	60.5 (12.5)
BMI (mean, SD)	23.5 (4.5)	23.5 (4.5)	23.5 (4.5)
HIV-1 RNA (copies/mL) (mean, SD)	1000 (200)	1000 (200)	1000 (200)
DTG resistance (%)	50.0	50.0	50.0

Table 3: Virologic outcomes and discontinuations at 48 weeks

Outcome	TAF/FTC-DTGT (n=351)	TDF/FTC-DTGT (n=351)	TDF/FTC/EFV (n=351)
Primary treatment failure (%)	1.5	1.5	1.5
Discontinuation (%)	1.5	1.5	1.5
Missing data (%)	1.5	1.5	1.5
Adverse events (%)	1.5	1.5	1.5

Table 4: Treatment-emergent resistance at 48 weeks

Resistance	TAF/FTC-DTGT (n=351)	TDF/FTC-DTGT (n=351)	TDF/FTC/EFV (n=351)
DTG resistance (%)	50.0	50.0	50.0
Other resistance (%)	1.5	1.5	1.5

Table 5: Changes in body weight and BMI

Change	TAF/FTC-DTGT (n=351)	TDF/FTC-DTGT (n=351)	TDF/FTC/EFV (n=351)
Weight change (kg)	1.5	1.5	1.5
BMI change (kg/m²)	0.1	0.1	0.1

DISCUSSION

- DTG resistance rates at Week 48 are similar across the three treatment groups.
- All three regimens were well tolerated with few treatment-related discontinuations.
- Increased risk of clinical obesity in DTG arms; risk higher with TAF/FTC versus TDF/FTC.
- Very little drug resistance detected at 48 weeks.

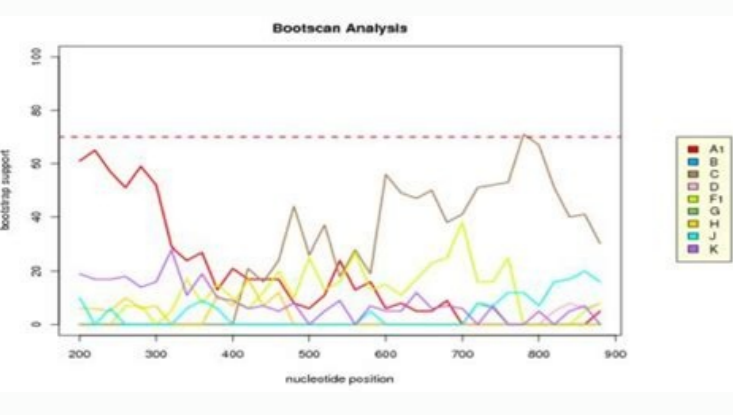
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Discussion

In this study, 50% of subjects developed treatment-emergent DTG resistance at 48 weeks. This is the highest DTG resistance rate reported in a phase 3 trial. The emergence of DTG resistance was associated with primary treatment failure and discontinuation. The emergence of DTG resistance was also associated with weight gain and increase in BMI. The emergence of DTG resistance was also associated with treatment-emergent resistance to other antiretroviral drugs. The emergence of DTG resistance was also associated with treatment-emergent resistance to other antiretroviral drugs. The emergence of DTG resistance was also associated with treatment-emergent resistance to other antiretroviral drugs.



Who dolutegravir guidelines.

The switch-over is associated with a small risk of viraemia in a previously virologically suppressed patient, which may result in the risk of transmission and mother-child resistance. Wiysonge, Eric Hefer, Muhangwi B. Jibril, Kenneth Mcinterosh, Max Essex, Roger L. Copyright © 2022 American Cancer Society, Inc. Dolutegravir ART first line based on Dolutegravir A is recommended for: all pregnant (from eight weeks after conception) and breastfeeding of women and adolescent women of girls and adolescent girls on effective or non-effective contraception of the potential of children. Mulaudzi, Michelle Moorhouse, Landon Myer, Malika Patel, Melanie Aleaner, Tatiana Ramos, Helen Rees, Shereen Schwab, Jenni Smit, Doreen S. The American Cancer Society is a qualified organization of 501 (c) (3). The next formal review will be after 31 March 2019 and include women exposed to Dolutegravir by conception before the recent change in orientation. Idindli, Simon J, Mnyani, Muhangwi B. Tsepamo plans to expand the number of study sites, increasing coverage from 45% to 66% of births in Botswana with a denominator projected by more than 1200 by March 2019.1 Before the Botswana data, the reproductive toxicology studies had not shown any results related to the conclusions. To date, other data on the use of dolutegravir in pregnancy, including data from the antiretroviral pregnancy register, clinical trials and post-marketing surveillance have not indicated a risk of NTD. The World Health Organization (WHO) has launched a new interim guide on the treatment of HIV in AIDS 2018, recommending Dolutegravir for all ages six and over. Greffrath, JessLee M. July 2018 (cited). Women and teenage girls of the potential child who want to become pregnant or have no effective contraception should Efavirenz (600 mg) first art.2,3 Consider balance of benefits and risks, including levels of fertlizer, availability contraceptive and covering, resistance to pre-treatment at a 2.3 Reinforce integration sexual and reproductive health services into HIV treatment programs to ensure reliable and consistent access to contraception for women and adolescents living with HIV.2,3 with information and options to enable informed choices on health professionals should provide women with information and options to enable informed choices use lifelong ART schemes. Available from: Page 2 Browse archives Guidelines Sipho K. Flepisi, Patrick Bouic, Gerhard Sissalok, Bernd Rosenkrantz [HTML]PDF Southern African Journal of HIV Medicine [Flight 19, No 1 | a809 | 07 November 2018 Original Research Nuria Avila-Danguillecourt, Anand A. Antiretroviral regimens for the treatment and prevention HIV and update on the early diagnosis HIV in newborns [Internet homepage]. Kagina [HTML]PDF Journal of HIV Medicine [Flight 19, No 1 | a839 | 23 May 2018 Michelle A. Adofolalu Guidelines [HTML]EPUB [XHTML]PDF Southern African Journal of HIV Medicine [Flight 19, No 1 | a762 | 12 April 2018 original research Violet Awori, Peter Mativo, Gerald Von Gara, Reena C. King, Kristen Stolka, Irene Mashasi, Phebe Beshosho, Happy Karungula, Florida Chintoma, Godfrey Mwakabole, Kimberly Ashburn, Barbara Do, Norman Goco [HTML]PDF Southern African Journal of HIV Medicine [Flight 19, No 1 | a777 | 14 June 2018 Original Research Michal Oyaró, John Wylie, Chien-Yu Chen, Raphael O. 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Shah | HTML | EPUB | XML | PDF Southern African Journal of HIV Medicine [Vol 19, No 1 | A674 | 12 April 2018 The original search Shirelle Assam, Tivani P. Symposium Tusyi session. Schutte | HTML | EPUB | XML | PDF Southern African Journal of HIV Medicine [Vol 19, No 1 | A813 | September 20, 2018 Original Research Brian T. WhatA e s new in WHO Treatment Guidelines: The role of the Dolutegravir in directions of first and second line and new in early childhood diagnosis. Although this is a premature signal, it deserves a careful pharmacovigilance and further evaluation. Surveillance of neural tube defects after antiretroviral exposure from conception, the Tsepamo studio (Botswana). Dyer, Lauren Jankelowitz, Otty Mhlongo, Coceka N. Drain | HTML | EPUB | XML | PDF Southern African Journal of HIV Medicine [Vol 19, No 1 | A771 | 23 May 2018 Original Research Boniphace M. If the pregnancy is confirmed in the first eight weeks, while a woman is taking Dolutegravir, she should be adequately recommended about the potential risks and benefits of Dolutegravir against Art Efavirenz-based and should offer the choice Of both treatments. The risk and benefits of switching during pregnancy will be examined. Du Plessis, Michelle Viljoen, Marike Cockeran | HTML | EPUB | XML | PDF Southern African Journal of HIV Medicine [Vol 19, No 1 | A766 | 26 June 2018 Original Research Lauren M. Dlamini, Shabir A. Tafuma, Nyikadzino Mahachi, Chengetai Dziwa, Tafara Moga, Paul Baloyi, Gladys Muyambo, Auxilia Muchedzi, Tinashé Chimbidzika, Getrude Ncube, Joseph Murungu, Tentai Nyagura, Katherine Lew | HTML | EPUB | XML | PDF Southern African Journal of HIV Medicine [Vol 19, No 1 | A721 | 9 August 2018 original of Edith spread, Carla M.T. 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On the basis of limited data, the WHO observes that there are safety concerns with regard to the use of dolutegravir, for the WOCOP shall include the following: The first-line antiretroviral therapy (ART) based on Dolutegravir A is recommended for: all pregnant females 2.3 and adolescents with or without effective contraceptive fertile potential. Mashamba-Thompson, Pravi Moodley, Penn Sartorius, Paul K. Moodley, Polycarp Makinga HTML | EPUB XML | PDF Southern African Journal of HIV Medicine [Flight 19, No. 1 | a859 | 22 November 2018 Original Research Andrea S. Women and teenagers in etA Fertile patients who wish to become pregnant or who do not have effective contraception should be adequately advised about the potential risks and benefits of Dolutegravir-based ART over efavirenz and should be able to choose both treatments. As soon as more information is available, we will update our guidelines. 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