Klinikum rechts der Isar
Technische Universität München

DUALIS

A SWITCH TO DOLUTEGRAVIR IN COMBINATION WITH BOOSTED DARUNAVIR IS SAFE AND EFFECTIVE IN SUPPRESSED PATIENTS WITH HIV – A PREDEFINED PSYCHOSOCIAL SUBANALYSIS OF THE DUALIS STUDY

Joram Ronel[1], Bernhard Bührlen[2], Franz Fischer[2], Christoph Boesecke[3], Tim Kümmerle[4], Jochen Schneider[5], Christiane Cordes[6], Hans Heiken[7], Hans-Jürgen Stellbrink[8], Ivanka Krznaric[9], Stefan Scholten[10], Björn Jensen[11], and Christoph D. Spinner[5] on behalf of the DUALIS STUDY GROUP

[1]Department of Psychosomatic Medicine and Psychotherapy, Clinic Barmelweid, Barmelweid, Switzerland, [2]Peymeta, Clinical Research Organisation, Schaffsheim, Switzerland, [3]Bonn University Hospital, Bonn, Germany, [4]Private Practice am Ebertplatz, Cologne, Germany, [5]Technical University of Munich, School of Medicine, Munich, Germany, [6]Private Practice, Berlin, Germany, [7]Private Practice Georgstrasse, Hannover, Germany, [8]ICH Study Center, Hamburg, Germany, [9]Private Practice Zentrum für Infektiologie Prenzlauer Berg, Berlin, Germany, [10]Private Practice Hohenstaufenring, Cologne, Germany, [11]University Hospital Düsseldorf, Düsseldorf, Germany, on behalf of the DUALIS Study Group

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Purpose

The DUALIS study assessed a combination of Dolutegravir (DTG) and boosted Darunavir (bDRV) (2DR) for maintaining HIV-suppression and demonstrated non-inferiority as compared to 2NRTI+bDRV (3DR). A predefined psychosocial sub-analysis focused on psychopathology and health related quality of life (HRQoL).

Methods

The study sample of the exposed intention-to-treat (ITTe) population consisted of n=263 pre-dominantly male Caucasian persons with a mean age of 46.7 years.[1] All patients completed a sociodemographic questionnaire together with two validated outcome instruments: The Hospital Anxiety and Depression Scale (HADS) with two scales and the Medical Outcomes Study HIV Health Survey (MOS-HIV) with 11 scales characterizing HRQoL.
Multiple logistic regressions were carried out for each dichotomized outcome criterion (> vs. ≤ median scores) at the last visit (48 weeks after enrollment) with treatment arms as group factor (2DR vs. 3DR) and baseline value of the outcomes, age, sex, population size of the patients' area of residence, current occupation and current or earlier treatment for mental disorder as covariables. Odds ratios (OR) and their 95% confidence intervals (CI) for the 2DR group as compared to the 3DR group were computed.

Results

The study groups did not differ with regard to sociodemographic factors.
Odds ratios (OR; 95% CI) of the two HADS subscales, anxiety (0.76; 0.42-1.38) and depression (0.73; 0.41-1.30), as well as the OR of the 11 HRQoL scales of the MOS-HIV scale, including physical functioning (0.64; 0.34-1.21), role functioning (0.55; 0.21-1.38), mental health (0.75; 0.41-1.37), energy (1.02; 0.55-1.90), health distress (0.78; 0.40-1.53), cognitive functioning (0.78; 0.42-1.44), overall health (1.30; 0.70-2.42), pain (0.75; 0.43-1.31), social functioning (0.81; 0.44-1.46), quality of life (0.59; 0.31-1.12) and health transition (1.01; 0.51-1.99), until 48 weeks of treatment did not show significant differences (figure 1).

Conclusion

A switch to a 2DR regimen consisting of DTG+bDRV does not lead to any significant differences, neither in anxiety nor depression, nor in HRQoL outcome measures.

Acknowledgment

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References

1 Spinner C. et al. 10th IAS Conference, Mexico, July 21-24, 2019, #MOPEB269.

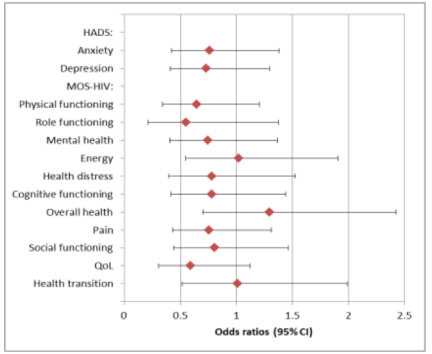

Figure 1: Forest plot showing the adjusted odds ratios and the corresponding 95% confidence intervals (95% CI) for HADS and MOS-HIV binary subscale outcomes (> vs. ≤ median values) at week 48, comparing 2DR and 3DR.

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