Universität Basel

Research Project

Identifying most effective Treatment Strategies to control Arterial Hypertension in sub-Saharan Africa - A Randomized Controlled Trial

Third-party funded project

Project title Identifying most effective Treatment Strategies to control Arterial Hypertension in sub-Saharan Africa - A Randomized Controlled Trial
Principal Investigator(s) Weisser, Maja ; Labhardt, Niklaus ; Burkard, Thilo ;
Co-Investigator(s) Mapesi, Herry ; Rohacek, Martin ;
Project Members Paris, Daniel Henry ; Fink, Günther ; Glass, Tracy ; Battegay, Manuel E. ; Vanobberghen, Fiona ; Gupta, Ravi Shankar ; Gingo, Winfried ; Muhairwe, Josephine ; Kalinjuma, Aneth Vedastus ;
Organisation / Research unit
Faculty of Medicine
Departement Biomedizin / Department of Biomedicine, University Hospital Basel
Bereich Medizinische Fächer (Klinik) / Infektiologie (Battegay M)
Department
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Background. The rollout of antiretroviral treatment (ART) has led to a dramatic reduction in HIV/AIDS-associated deaths, but resulted in a remarkable increase of cardiovascular mortality. Arterial hypertension is the most prevalent risk factor for cardiovascular disease. The Sub-Saharan African region is particularly burdened by both diseases, with both the prevalence of HIV and the prevalence of arterial hypertension rates exceeding those of most other regions. Management of arterial hypertension in sub-Saharan Africa, especially in rural settings, remains poor due to low awareness in communities and among health workers, lack of screening programs, high cost of antihypertensive medication and the general lack of evidence regarding optimal antihypertensive treatment for Africans living in sub-Saharan Africa.

Rationale. The World Health Organization (WHO) recommends starting treatment of arterial hypertension with a thiazide diuretic and adding a calcium antagonist if the target blood pressure is not achieved. Newer antihypertensive drugs and treatment strategies are available but have never been compared to the WHO approach in Africa. With the proposed randomized controlled trial, we aim at closing this evidence gap, comparing the current standard of care WHO algorithm with two alternative treatment strategies aiming at rapid control of arterial hypertension: a dual combination of thiazide diuretic and an angiotensin-receptor blocker, and a low-dose triple combination with optional dose titration.

Overall objectives. To inform future guidelines and policies on care for patients with arterial hypertension in sub-Saharan Africa.

Specific aims. The main objective is to conduct in an open-label, two-country, controlled randomized trial to assess three antihypertensive treatment strategies in HIV-positive and HIV-negative patients: the current WHO-recommended treatment and two alternatives, potentially more cost-effective treatments. The trial will focus on patients with uncomplicated arterial hypertension. It will be conducted in partnering hospitals in Tanzania and Lesotho and compare both the effectiveness, safety and cost-effectiveness of the three strategies. The primary outcome is reaching a target blood pressure of č130/80mmHg for patients aged <65years and č140/90mmHg for patients aged ş65years within 12 weeks of treatment ini-

tiation. As secondary objectives we will assess mean reduction of blood pressure at different time points, clinical outcomes such as mortality, major cardiovascular events and surrogate markers of clinical outcomes (proteinuria, creatinine, retinopathy, hypertensive heart disease). We will also assess adverse events and the cost-effectiveness of the three treatment strategies over a 24-week period and the comparability of different blood pressure measurement techniques in this setting.

Expected results. We expect to generate evidence on the most effective and cost-effective pharmacologic treatment strategies for patients with uncomplicated arterial hypertension in resource-limited settings in rural Africa. Furthermore, we will contribute knowledge to additional aspects of care for arterial hypertension, such as optimal approach for blood-pressure measurement and assessment of clinical surrogate markers.

Impact of the study. The proposed randomized trial will inform future guidelines on management of arterial hypertension in sub-Saharan Africa and contribute to policies on blood pressure control in resource-limited settings.

Keywords Hypertension, sub-Saharan Africa, drug treatment
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