東独臨床試験問題：冷戦下に起きたこと

齊尾　武郎[1)*]　　栗原千絵子[2)]
1）フジ虎ノ門整形外科病院内科・精神科
2）国立研究開発法人量子科学技術研究開発機構放射線医学総合研究所

East German scandal on clinical trial: At the height of the Cold War

Takeo Saio[1)]　　Chieko Kurihara[2)]
1）Department of Internal Medicine and Psychiatry, Fuji Toranomon Orthopedic Hospital
2）National Institute of Radiological Sciences, National Institute
for Quantum and Radiological Science and Technology

Abstract
Background：In May 2013, the prestigious German journal *Der Spiegel* reported the clinical trials sponsored by the Western pharmaceutical companies in the former East Germany (German Democratic Republic: GDR) during the Cold War era as unethical with testimonies of research subjects and other related people. After that, Erices R, et al. reported their analysis on the archival material of both the health system and the secret service in the *Journal of Medical Ethics* in October 2014. Most recently in March 2016, Hess et al. published an academic book with more detailed analysis of this issue with historical materials.
Objectives：To identify characteristics of the clinical trials conducted in the former GDR sponsored by the Western companies and ethical problems beneath.
Methods：Literature review of the three reports mentioned above.
Findings：First, from the viewpoint of medical ethics, it is most alarming that a number of clinical trials had been performed without informed consent of the subjects. Second, the journal *Der Spiegel* condemned some ethically questionable trials, e.g. placebo controlled trial of an anti-hypertension drug. Meanwhile, both of the academic reports of Erices R, et al. and Hess et al. concluded that there was not so serious a deviation except the issue of informed consent and pointed out the possibility of the benefit from these trials in GDR where resources of medication were limited. Third, they revealed the complicated relationships among the political authorities of GDR and the Western pharmaceutical companies.
Conclusions：These three reports revealed the hidden facts around these trials performed in the former East Germany during the Cold War era, but more analysis is needed especially from the viewpoint of 1) informed consent; 2) possibility of unjustifiable harm; and 3) exploitation of research subjects.

Key words
German Democratic Republic (GDR), Cold War, clinical trial, informed consent, exploitation

Rinsho Hyoka（*Clinical Evaluation*）. 2016；44：299-306.

＊ K&S産業精神保健コンサルティング（K&S Consulting Office for Occupational Mental Health）