

Abstract

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**The study of reactogenicity, safety, and immunogenicity of recombinant
smallpox-and hepatitis B vaccine for oral administration in humans**

**Sergeev A.N.¹, Plyasunov I.V.¹, Sergeev A.A.¹, Kuzubov V.I.², Maximov V.A.³, Melnikov
S.A.³, Drozdov I.G.¹**

¹FSRI State Research Center of Virology and Biotechnology VECTOR, Rospotrebnadzor,
Koltsovo, Novosibirsk region 630559, Russian Federation;

²FSPHI “Medical and Sanitary Unit #163”, Federal Medico-Biological Agency, Koltsovo,
Novosibirsk region, Russian Federation;

³Virological Center of RI of Microbiology, Sergiev Posad, Russian Federation

Corresponding author: A.N.Sergeev, State Research Center of Virology and Biotechnology
VECTOR, Koltsovo, Novosibirsk region, 630559, Russian Federation; tel/fax: (383-2)-36-74-
68; e-mail: serg@vector.nsc.ru

In cooperation with the Virological Center “Research Institute of Microbiology”, clinical trials have been completed in a limited group of human volunteers under conditions of remote and primary vaccination to study the reactogenicity, safety and immunogenicity of the “Embryonic live recombinant smallpox-and-hepatitis B bivalent vaccine, tablets (Revax-BT)”.

Double oral administration of this bivalent vaccine to volunteers (at a low and a higher dose) at a 1–2-week interval between the administrations caused, at a maximum, only mild local or general reactions, creating a 90 - 100% immune cohort among volunteers against smallpox. Within not less than 6 months, the immunity strength to vaccinia virus remains at a protective level in $\geq 70\%$ of volunteers. Double immunization with the bivalent vaccine of volunteers previously immunized against hepatitis B generates immunity to this infection in 88% of immunized volunteers. In double immunization of volunteers with the bivalent vaccine under conditions of primary and remote vaccination (even when local or general reactions were observed in the volunteers), the presence of recombinant vaccinia virus in the tested blood, saliva and urine samples was reported in none of the cases.

Thus, an optimal scheme was identified to permit oral immunization of volunteers against smallpox with the bivalent vaccine, under conditions of primary or remote vaccination, that involves double administration of the vaccine (at a lower followed by a higher dose) at 1-2 week intervals. Based on these findings, FSRI SRC VB VECTOR is in the process of obtaining the Russian Federation the Ministry of Health and Social Development approval to initiate state clinical trials of this vaccine.