Protection against clinical mpox disease: What is needed?

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Background: Mpox, a zoonotic disease caused by the monkeypox virus, has emerged as a global health threat following the 2022 outbreak, with ongoing transmission of different clades, particularly in Africa. While primary vaccination with MVA-BN was scaled up in high-risk groups, evidence of waning serum antibodies and breakthrough infections suggests that immune protection may decline over time, necessitating evaluation of booster strategies to maintain long-term efficacy and simultaneously address vaccine dose limitations.

Materials and Methods: In this randomized non-inferiority trial, 640 participants recruited in Belgium, France, Ireland and Sweden, receive a booster vaccination with either 0.5 ml MVA-BN subcutaneously or 0.1 ml intradermally, or are assigned to a control group offered a booster after 6 months. Immune responses (ELISA, neutralizing antibodies, B cell, T cell, and mucosal immunity) and safety are assessed at baseline, 1 month, and up to 24 months.

Results: Preliminary analysis of the antibody response at one month post booster dose, ie the primary outcome, will be presented. Results will be discussed in the light of an updated description of the current mpox epidemiology. The formation of an EU wide trial platform will be presented.

Conclusion: This trial, performed by a multi-country consortium established in the time of a public health emergency, will provide critical evidence on the safety and immunogenicity of booster protection, supporting EU and global mpox vaccine policies and pandemic preparedness. Mechanisms enabling rapid funding, ethical approval, and multinational collaboration must be established to support effective responses to public health emergencies.