ANRS 0576s UNITY - Information for research participants

Title : A phase III, multi-country, randomized, placebo-controlled, double-blinded trial to assess the efficacy and safety of tecovirimat antiviral treatment for patients with monkeypox virus disease

In brief	Structures /teams : For Argentina, National coordinating investigator : Dr. Pedro Cahn, Fundación Huésped, Ciudad Autónoma de Buenos Aires, Argentina; For Brazil, National coordinating investigator : Pr. Beatriz Grinsztejn, HIV/STI Clinical Trials Unit, National Institute of Infectious Diseases Evandro Chagas – Fiocruz, Rio de Janeiro, Brazil; For Switzerland : Sponsor representative and national coordinating investigator in Switzerland : Pr. Alexandra Calmy ; HIV/AIDS unit, Division of Infectious Diseases, Geneva University Hospitals, Geneva, Switzerland.
	Start date : March 03, 2023 Inclusions completed : May 8, 2025 End date of research: planed on November 2026
	Number of participants : 480 participants randomized
	Research status: In progress
	Pathology: mpox virus infection
	Promotion: Inserm - ANRS MIE
	Funded under: MPX Response
The project	Brief description of research ANRS 0576s UNITY is an international trial (Argentina, Brazil and Switzerland) aiming to assess the efficacy and safety of tecovirimat as an antiviral treatment in adults and adolescents (14 years old and older) with a confirmed mpox virus infection. The study includes one arm where participants are randomised to receive either the active drug or placebo, and an open-label arm to provide tecovirimat to participants with severe manifestation of the diseases or at risk of severe complications. Detailed analyses will also enable to establish the relationship between the concentration of tecovirimat in blood and tissues and its efficacy, and to study potential resistance of the virus to tecovirimat.
Latest news	Analysis are in progress
Publication references	The international **Unity** study for antivirals against mpox is a blueprint for future epidemics. Telford E, Grinsztejn B, Olsen IC, Pulik N, Mentré F, Haviari S, Hentzien M, Ségéral O, Ekkelenkamp MB, Ogoina D, Strub-Wourgaft N, Diallo A, Yazdanpanah Y, Calmy A. Nat Med. 2023 Aug;29(8):1894-1895. doi: 10.1038/s41591-023-02393-6.
Type of study	Drug trial, international and multicenter
Main objectives	The primary objective is to evaluate the clinical efficacy, assessed as time to all visible lesion(s) resolution, of tecovirimat treatment + Standard of Care (SOC) compared to placebo + SOC for patients with mpox infection.
Secondary objectives	The secondary objectives are 1- To evaluate the safety and efficacy, assessed as time to active lesions resolution, mortality, hospitalization, complications, duration of symptoms and virological shedding of tecovirimat treatment + SOC compared to placebo + SOC in patients with mpox infection

	2- To explore the clinical efficacy of tecovirimat treatment + SOC in patients with severe complications and/or at risk of severe complications The Exploratory objectives are 1- To assess compliance- and exposure-response relationships 2- To determine the impact of covariates on tecovirimat plasmatic concentration 3- To assess relationships between exposure, in each compartment (blood, skin, mucosae), and emergence of tecovirimat drug-resistance associated mutations 4- To assess exposure-response-transmission relationships using tecovirimat-sample-exposed culture results, and by integration with external data on viral load and transmission 5- To characterize viral load kinetic over time in blood and compartments by PCR and viral culture 6- To investigate tecovirimat drug resistance testing by viral sequencing and phenotypic assay in positive samples 7- To assess the effect of early humoral immune response on viral clearance dynamics Analysis of exploratory objectives will be performed in public research laboratories located in France (In Marseille : IRD 190 and INSERM 1207 and Paris : Bichat Hospital and St Louis Hospital).
Optional: Link to research website	https://anrs.fr/fr/partenariats/projets-structurants-internationaux/projet-mpx-response-lutter-contre-la-variole-simienne-mpox/

Type of infection	**Withdrawals**
☐Covid-19	☐DNA
☐IST	☐RNA
☐Tuberculous meningitis	☐DBS
☒Mpox	☐Nasopharyngeal and oropharyngeal swab
☐Tuberculosis	☐PBMC (-80°C)
☐VHB	☐PBMC
☐HCV	☒Plasma
☐VHD	☐Saliva
☐HIV-1	☐Whole blood
☐HIV-2	☐Serum
☐Healthy volunteer	☐Urine
	☒Other sampling : Swabs of lesions
Population	

☒Teens

☒Adults

☐Children

COUNTRY

☒ Brazil

☐ Burkina Faso

☐ Cambodia

☐ Cameroon

☐ Ivory Coast

☐ Egypt

☐ Europe

☐ France

☐ Guinea

☐ Mali

☐ RDC

☐ Senegal

☐ Vietnam

☐ Zambia

If a new box is to be created, please specify:

☒ Argentina

☒ Switzerland
