

ANRS 0562s HIPOCAMP - Information for research participants

Title: HBV universal vs Point-Of-Care-based Antiviral treatment to Prevent mother-to-child transmission: a multi-country cluster-randomized non-inferiority trial

At a glance	Investigators:
	- Yusuke SHIMAKAWA, Institut Pasteur (France) - Didier EKOUEVI, CARESP (Togo) - Olivier SEGERAL, Geneva University Hospitals (Switzerland)
	Institution/teams:
	- yusuke.shimakawa@pasteur.fr - didier.ekouevi@gmail.com - olivier.segeral@hug.ch
	Start date: 08/2026
	Research end date: 3 rd quarter 2028
	Expected number of participants: 3,200 women
	Research status: Ongoing
	Condition: Hepatitis B virus
The project	Sponsor: Inserm - ANRS MIE
	Funded under call: 2024-1
	Mother-to-child transmission of the hepatitis B virus remains a major public health problem in low-resource countries. The World Health Organization recommends measuring the amount of virus in the blood of every pregnant woman living with HBV, to identify those at risk of passing the virus on to their baby who need preventive treatment (tenofovir). However, this test remains hard to access in many regions, especially in rural areas. WHO proposes a simpler alternative: treating all women living with HBV, without knowing their viral load. This strategy simplifies care, but means treating many women who would not need it.
	HIPOCAMP is being conducted in 4 countries (Vietnam, Cameroon, Côte d'Ivoire, Togo). It compares two prevention strategies during pregnancy: • Strategy 1: systematically treating all women living with the virus with tenofovir. • Strategy 2: targeting treatment using a new rapid test that can be performed on site (point-of-care), without a laboratory
	The study will measure whether women take their treatment, remain in care and whether the amount of virus decreases by delivery. An additional component looks at women's experiences and at the acceptability of each approach. 3,200 women living with HBV will be enrolled and followed up until 9 months after delivery.
	First enrolment: 10 August 2026 (in Vietnam)
	Two countries open: Vietnam and Côte d'Ivoire
Latest news (if applicable)	
Publication references (if applicable)	

Study type	RIPH 2
Primary objectives	To assess whether a targeted strategy using the innovative high-sensitivity HBeAg rapid diagnostic test in HBV-infected pregnant women at decentralised sites is non-inferior to a universal strategy, in which all HBV-infected women receive tenofovir (TDF) prophylaxis, in terms of retention in care and reduction of HBV DNA levels at delivery.
Secondary objectives	1. To estimate the risk of HBV infection in children at nine months in each strategy. 2. To assess the cost and cost-effectiveness of both strategies. 3. To compare the acceptability, appropriateness and feasibility of the strategies. 4. To assess all serious adverse events and adverse events of special interest occurring in women and children taking part in the study. 5. To assess postpartum linkage to care and identify barriers and facilitators. 6. To assess women's knowledge of HBV and their health literacy. 7. To explore women's disclosure of their HBV status to their partners and children, as well as their perceptions and experiences of testing their partners and children.
Optional: Link to the research website	

A – Overall research results

B – Secondary use of data and samples (Delete if not needed)

B – Secondary use of data and samples

This section concerns participants who were enrolled in the research and consented to the reuse of their data and/or samples. Through its website and this document, the research sponsor informs you of projects involving the secondary use of your data and/or samples.

B1. For the not-yet-started projects listed below only, you may object to the secondary use of your samples and/or data. To do so, please send an email to the following address dpo@inserm.fr stating the name of the research and the title of the project for which you refuse the reuse of your data and/or samples, no later than one week before the planned start date of the project. If you have not exercised your right to object before the project starts, please note that the data and/or samples already processed cannot be erased, insofar as their erasure would be likely to make impossible or seriously compromise the achievement of the research objectives.

Not-yet-started projects (Note: information on any reuse must be made available to participants at least 1 month before the data and/or samples are actually used)

Project title	
Project summary	
Planned project start date	
Data recipients in France	
Data recipients outside France	
Identity of the data controller	
Transfer of data and/or samples	
Planned retention period for data and/or samples for this project (<i>from the project start date</i>)	
Data categories	

B2. For the ongoing projects listed below, it is not possible to object, insofar as erasure of the data would be likely to make impossible or seriously compromise the achievement of the research objectives.

Ongoing projects

Project title	Universal versus targeted antiviral treatment of hepatitis B virus (HBV) to prevent mother-to-child transmission: a multi-country cluster-randomised non-inferiority trial
Project summary	Mother-to-child transmission of the hepatitis B virus remains a major public health problem in low-resource countries. The World Health Organization recommends measuring the amount of virus in the blood of every pregnant woman living with HBV, to identify those at risk of passing the virus on to their baby who need preventive treatment (tenofovir). However, this test remains hard to access in many regions, especially in rural areas. WHO proposes a simpler alternative: treating all women living with HBV, without knowing their viral load. This strategy simplifies care, but means treating many women who would not need it. HIPOCAMP is being conducted in 4 countries (Vietnam, Cameroon, Côte d'Ivoire, Togo). It compares two prevention strategies during pregnancy: • Strategy 1: systematically treating all women living with the virus with tenofovir. • Strategy 2: targeting treatment using a new rapid test that can be performed on site (point-of-care), without a laboratory The study will measure whether women take their treatment, remain in care and whether the amount of virus decreases by delivery. An additional component looks at women's experiences and at the acceptability of each approach. 3,200 women living with HBV will be enrolled and followed up until 9 months after delivery.
Project start date	August 2026
Planned project end date	Mid-2028
Data recipients in France	Institut Pasteur (France) SESSTIM (France) ORS PACA (France)

Data recipients outside France	Geneva University Hospitals (Switzerland) CARESP (Togo) PAC-CI (Côte d'Ivoire) ANRS Cameroon site (Cameroon) Hai Phong University of Medicine and Pharmacy (Vietnam)
Identity of the data controller	Inserm ANRS MIE
Transfer of data and/or samples	Data
Retention period for data and/or samples for this project (<i>from the project start date</i>)	15 years
Data categories	Identification data Health data Data relating to the conduct of the research Lifestyle data Family situation data Professional life data Economic situation data

B2. For completed projects, it is not possible to object, insofar as erasure of the data would be likely to make impossible or seriously compromise the achievement of the research objectives.

Completed projects

Project title	
Project summary	
Project start and end dates	
Data recipients in France	
Data recipients outside France	
Identity of the data controller	
Transfer of data and/or samples	
Retention period for data and/or samples for this project (<i>from the project start date</i>)	
Data categories	
Overall project results	