

ANRS 0562s HIPOCAMP - Information for researchers

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:
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	Start date: 08/2026
	Research end date: 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.
	Latest news (if applicable)
	First enrolment: 10 August 2026 (in Vietnam)
	Two countries open: Vietnam and Côte d'Ivoire
	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	
Inclusion criteria	Age: ≥ 18 years at the date of enrolment Pregnancy: confirmed Antenatal care: intention to continue antenatal visits at the PHC or RH Residence: home located in the catchment area of the PHC or RH at the trial start date HBsAg status: positive, identified at screening Consent: free, informed and signed consent before any study-related procedure
Exclusion criteria	HIV co-infection Ongoing HBV treatment on the day of enrolment At least one of the following criteria indicating the third trimester of pregnancy: a) Exclusion based on gestational age: reported gestational age ≥ 28 weeks (based on last menstrual period if known) b) Exclusion based on ultrasound: fetal biometry (e.g. head circumference, femur length) suggesting a gestational age ≥ 28 weeks c) Exclusion based on fundal height: SFH measurement ≥ 28 cm (corresponding to an estimated gestational age ≥ 28 weeks) Severe pregnancy-related condition at enrolment, endangering the life of the mother or child Any concomitant illness that, in the investigator's opinion, contraindicates participation

	in the study Simultaneous participation in another study without the written agreement of the global principal investigators
Primary outcome	The primary outcome will be the percentage of HBsAg-positive women presenting at a health facility for delivery with an HBV viral load (DNA) < 200,000 IU/mL at delivery. This outcome will be assessed at cluster level. HBV DNA results for women delivering outside the study site will also be included if the test was performed on a blood sample collected between delivery and one week postpartum. Women lost to follow-up and/or without an HBV DNA measurement after one week postpartum will be considered strategy failures.
Secondary outcomes	1. % of children HBsAg-positive at 9 months of age 2. % of PAP-eligible women who started TDF on the same day as HBsAg screening 3. % of PAP-eligible women who completed TDF prophylaxis until delivery 4. % of women with adherence > 90% at each study visit based on pill count and visual analogue scale, from enrolment to delivery 5. % of children receiving the HBV birth-dose vaccine (HepB-BD) within the recommended timeframe 6. % of children with a complete HBV vaccination schedule 7. % of women or children experiencing a serious adverse event (SAE) leading to death or treatment discontinuation before delivery, and adverse events of special interest 8. % of women who received a liver disease assessment at 3 months postpartum, and factors associated with retention in care 9. % of women eligible for long-term TDF treatment at 3 months postpartum according to the 2024 WHO guidelines 10. Accuracy (sensitivity, specificity, positive and negative predictive values) of the simplified score (HBeAg-hs-RDT & ALT) for predicting eligibility for long-term TDF treatment, using the 2024 WHO guidelines as the reference 11. Knowledge score on hepatitis B and associated risks, empowerment and health literacy (communicative literacy, COM-HL scale) among women and healthcare professionals, and associated factors 12. Measures of HBV status disclosure among women (% who disclosed their status to their partner, HBV disclosure score), experience of status disclosure (moral support and discrimination scales) and associated factors 13. % of partners and children tested for HBV 14. Measures of perceived health and quality of life among women, assessed using the Patient Health Questionnaire-4 (PHQ-4), the Edinburgh Postnatal Depression Scale (EPDS) and the Internalized Stigma of Mental Illness scale (ISMI), and associated factors 15. Acceptability of and preferences for each strategy among healthcare professionals 16. Costs and cost-effectiveness of the selective strategy compared with the universal strategy, and determination of whether the selective strategy offers a specific benefit for certain socio-economic groups

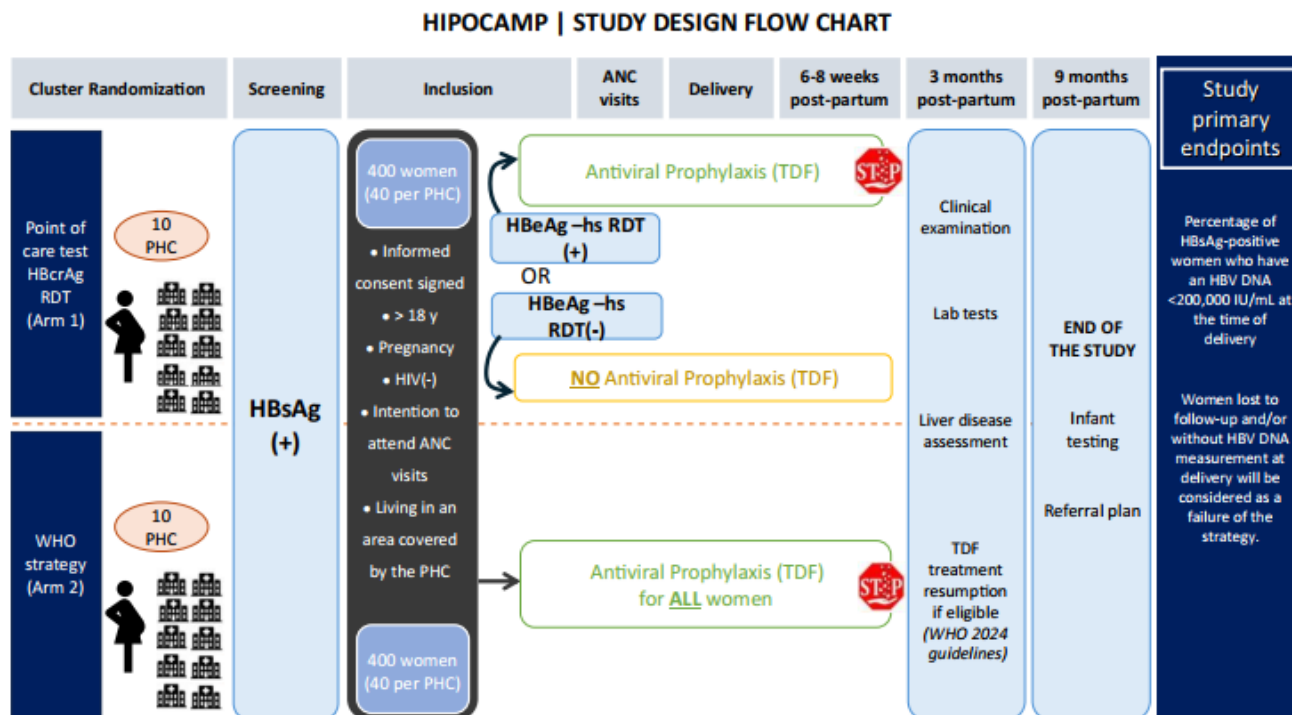
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- A – Study methodology and type of data and/or samples collected
- B – Procedures for accessing the collection

A – Study methodology and type of data and/or samples collected

Data and samples collected	Biobanks	Plasma and DBS
	Data	Clinical, biological, socio-economic, behavioural (quantitative), health policy

Add the study design diagram if available



Add the sampling schedule if applicable:

- Inclusion, delivery and 3 months post-partum

Specify the follow-up schedule (annual, six-monthly, etc.):

- Visits according to each country's antenatal care schedule

B – Procedures for accessing the collection

- 1- project submission: **via the sample request form on the website**
 - 2- project evaluation: **scientific committee or independent experts**
 - 3- Release of the collection: **final decision by ANRS MIE management or scientific council**
- Contact email address for submitting your project: **biobanque@anrs.fr**