Development of a Predictive Model for Sexually Transmitted Infections in Individuals Using Pre-Exposure Prophylaxis for HIV in Spain

Principal Investigator: Anaïs Corma Gómez
Version 1

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PATIENT INFORMATION SHEET

"Development of a Predictive Model for Sexually Transmitted Infections in Individuals Using Pre-Exposure Prophylaxis for HIV in Spain"

Before signing this informed consent, please carefully read the following information and ask any questions you may have.

Nature of the Study

This project focuses on addressing HIV prevention in vulnerable groups, including men who have sex with men, transgender women, and heterosexual cisgender individuals at risk of acquiring HIV infection and who are enrolled in pre-exposure prophylaxis (PrEP) programs. PrEP is a preventive measure that involves taking medication to reduce the risk of HIV infection, along with clinical visits where potential sexual health risks are assessed, certain infections are prevented through vaccination of susceptible individuals, and tests are conducted to detect sexually transmitted infections (STIs).

Significance

Among these individuals, the risk of acquiring an STI is higher than in the general population. However, not all PrEP users face the same level of risk for developing an STI. Although PrEP is an effective intervention, its implementation faces challenges, particularly due to increasing demand that current PrEP-providing units are not fully equipped to handle. This project aims to improve STI detection and treatment among PrEP users by employing artificial intelligence to develop personalized predictive models.

By establishing a system that stratifies patients based on their risk of developing an STI, it would be possible to conduct more intensive follow-up for high-risk individuals while maintaining a less stringent approach for lower-risk individuals—ensuring patient safety while preventing service overload and unnecessary expenses. The project's expected outcomes include optimizing healthcare resources, enabling more efficient and personalized care, reducing the burden of STIs, and improving the quality of life of PrEP users while also preventing HIV transmission.

Implications for the Patient

Participation in this study is entirely voluntary. You may not experience direct benefits from participating in this research. You may withdraw from the study at any time, without providing an explanation and without it affecting your medical care. All personal data collected in this study is confidential and will be handled in accordance with Spain’s Organic Law on Personal Data Protection (3/2018). The information obtained will be used exclusively for the specific purposes of this study.

Potential Risks for the Patient

Participation in this study does not entail any additional risks. You will receive the necessary medical care if required. We will solely collect data derived from this medical care. Periodic visits will be conducted to monitor your clinical progress, following standard procedures for patients like you. The clinical data collected in the database for individuals enrolled in the study will be used exclusively for research purposes and will be treated with the utmost confidentiality.

For additional information, you may contact the principal investigator of this study at:
Phone: +34 961 973 500 (extension 436343)
Email: anais.corgo@gmail.com

INFORMED CONSENT

WRITTEN CONSENT OF THE PATIENT

Development of a Predictive Model for Sexually Transmitted Infections in Individuals Using Pre-Exposure Prophylaxis for HIV in Spain

I, (Full Name):

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- Have read the information document accompanying this consent form (**Patient Information Sheet**).
- Have had the opportunity to ask questions regarding the study **"Development of a Predictive Model for Sexually Transmitted Infections in Individuals Using Pre-Exposure Prophylaxis for HIV in Spain."**
- Have received sufficient information about the study **"Development of a Predictive Model for Sexually Transmitted Infections in Individuals Using Pre-Exposure Prophylaxis for HIV in Spain."**
- Have discussed the study with the healthcare professional providing the information:

  .....
- Understand that my participation is voluntary and that I am free to participate or not in the study.

I have been informed that this research study will be conducted in accordance with the ethical principles outlined in the **Declaration of Helsinki** of the **World Medical Association (WMA)**, **Law 14/2007 on Biomedical Research**, **Law 41/2002 on Patient Autonomy and Rights and Obligations Regarding Information and Clinical Documentation**, **Organic Law 3/2018 on Personal Data Protection and Digital Rights**, the principles of **Good Clinical Practice**, and the requirements of regulatory authorities for the verification of original documents and the audit/inspection of the study.

All data obtained in this study will remain **confidential** and will be processed in accordance with **Organic Law 3/2018 on Personal Data Protection**.

I wish to be informed of my personal data and any other information obtained during the course of the research, including unexpected findings, provided that such information is necessary to prevent serious harm to my health or that of my biological relatives.

☐ **Yes**
☐ **No**

I understand that I may withdraw from the study:

- At any time
- Without providing any explanation
- Without it affecting my medical care

In the event of withdrawal, the data obtained prior to my revocation MAY still be used.

I **freely** consent to participate in the project titled **"Development of a Predictive Model for Sexually Transmitted Infections in Individuals Using Pre-Exposure Prophylaxis for HIV in Spain."**

Patient's Signature

(or legal representative, if applicable)

Full Name: ……..
Date: ……

Healthcare Professional's Signature

Full Name: ……...
Date: ……

I wish to revoke my participation in the study.

Patient's Signature

(or legal representative, if applicable)

Full Name: ……..
Date: ……

Healthcare Professional's Signature

Full Name: ……...
Date: ……