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CONTROL

New in HIV prevention

Pre-HIV drug treatment, prep

National HIV and Hepatitis Expert Group

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Summary

This guideline has been prepared by a national HIV and hepatitis expert group chaired by the National Institute for Health and Welfare, which consists of several authorities, third sector actors and representatives of those infected. The purpose of the guide is to create uniform practices for pre-exposure prophylaxis in Finland. The guidelines aim to ensure that the medication is targeted correctly and that the use of the medication is properly monitored. The introduction of Prep has been shown to reduce the number of new infections combined with intensified testing and early treatment of infections. Prepin has been shown to save costs when properly targeted.

Prep treatment would be best organized through public health care. The organizer must have knowledge of HIV infection, sexually transmitted diseases and behavior. In this way, a harmonized assessment of the need for prep treatment and access to treatment would be best achieved, and national monitoring and evaluation of treatment would be easier to carry out. A national monitoring system should be set up to monitor the efficacy and safety of prep treatment.

Prep is for people who are at high risk of getting HIV. There is indisputable evidence of the effectiveness of Prep in men who have sex between men. Prep should also be considered for other groups if the risk of infection is particularly high.

Those who are vulnerable to HIV should receive appropriate and up-to-date information on the PRP. Organizations working on HIV play an important role in this. In addition, health and social care must have sufficient information about prep so that people can also be referred from there to assess prep care.

This guideline is based on emtricitabine-tenofovir disoproxil combination therapy.

Prep can be used either daily, regardless of the frequency of sexual contact, or as needed in connection with sexual contact. Appropriate use is recommended only for men who have sex between men.

Prep provides an opportunity to reach people at high risk for HIV and other sexually transmitted diseases, as well as to find infections that have not yet been identified. When considering the initiation of prep, the suitability of other HIV protection methods and services that reduce risk behavior instead of or alongside prep must also be investigated. Necessary advice on the prevention of other sexually transmitted and / or blood-borne diseases should always be given in connection with Prep.

The effectiveness of Prep is based on the use of the medicine in accordance with the instructions, which must be supported and monitored. In addition, prep medication requires proper drug safety monitoring and regular testing for HIV and other sexually transmitted diseases. Participation in follow-up is a prerequisite for renewing a prescription.

Keywords: HIV, prep, pre-exposure medication, infection prevention

Sammanfattning

This is the case in which national groups of experiments on hiv and hepatitis are led by the Institute for Hälsa and Välfärd. The group is best represented by a representative of the third party sector and a representative of the person concerned. Syftet med anvisningen is intended to be used in Finland for prophylactic medicine, prep (pre-exposure prophylaxis), for exposure to HIV. In the case of animal health, it is necessary to ensure that the medicinal product is properly and adequately treated. Användningen av prep har konstaterats minska mängden smittor tillsammans med effekti- vare testning and tidig behandling av smittorna. Prep har visats spara kostnader när den set in tow.

Prep-behandlingen ordnas bäst via den offentliga hälsovården. The actor is ordinarily affected by HIV infection, sexually transmitted animals (sexually transmitted animals) and sexually infected animals. For this reason, the use of pre-treatment in the same way as before and within the meaning of the national rules and procedures. For upholstery and effects, the pre-treatment of the skin and the national upholstery system can be performed.

The risk of being exposed to a person is very high. Prep har en obestridlig effects på män som idkar sex med män. Prep bör övervägas också för andra grupper om risken för smitta är speciellt stor.

However, the group may not be affected by the relevant and actual information in the prep. The organization of the arbitrator may enter into a position. In addition, the company will be able to prepare in advance for social and personal use, in which case it will be possible for the person concerned to be involved in the preparation of pre-employment.

The method of treatment is preferably based on a combination of emtricitabine and tenofovir disoproxil.

Prep kan användas antingen dagligen oberoende av frekvensen av sexkontakter eller vid behov i samband med en sexkontakt. Användning vid behov rekommenderas enbart fän män som idkar sex med män.

Prep erbjuder en möjlighet att nå personer som har hög risk att smittas med hiv eller andra könss-jukdomar och att hitta smittor som ännu inte constaterats. In this case, the method is to be prepared in such a way that it can be used in the event that the method is used to measure human health and the patient is at least at risk from the same or the same preparation. I samband med prep ska man alltid också ge råd om hur man skyddar sig mot andra sjukdomar som smittar via sexkontakt och / eller blod.

The effects of the preparation are based on the requirements of the present invention. This means that the stomach and udervakas. This is preceded by adequate pre-treatment in the field of oral and oral testing. In addition, the recipe for the recipe is based on the manuscript.

Nyckelord: HIV, prep, medicinering före exponering, smittprevention

Contents

Introduction

The goal of preventive HIV work in Finland is to reduce new infections. However, the number of infections has not been significantly reduced. At present, about 170 new HIV infections are diagnosed in Finland every year. Stopping the HIV epidemic requires a multifaceted combination of social, behavioral and medical measures and the introduction of proven methods.

In the early 2010s, a new safe and effective means of preventing infections, pre-exposure prophylaxis, became available. Prep is used in people who are not infected with HIV but who are at high risk of becoming infected.

The World Health Organization (WHO) and the European Center for Disease Control (ECDC) recommend prep for those at high risk of infection. With the recommendations, the use of drug therapies has become more widespread both in Western countries and globally. Free or low-cost prep medication for users is already in use nationally or in the form of projects in most Western European countries.

The effectiveness of Prep has been shown in several controlled studies. The effectiveness of treatment depends on the user's commitment to drug treatment. In the studies, individuals who had used prep medication as directed did not show any infection. The effectiveness of Prep has also been shown to be very good when treatment has been started outside the studies as part of health care services. The use of Prep has been found to reduce the number of new infections, along with intensified testing and early treatment of infections.

According to modeling studies in Europe, prep saves costs when it is targeted at people at high risk of infection. Treatment for people living with HIV lasts for the rest of their lives, and the total cost of treatment is currently estimated at around 500,000 euros. Prep treatment is not permanent and is estimated to last for an average of about 4 to 5 years. The annual cost of prep medication with generic medicines is at its lowest a few hundred euros a month in Europe, but prices vary regionally and over time. In Finland, generic products are not yet in use, but will be on the market this spring.

Prep also provides a unique opportunity to include people at high risk of HIV and sexually transmitted infections in healthcare. These contacts can influence risk behavior in a variety of ways, such as providing guidance on condom use or help with sex or substance abuse, and finding previously undiagnosed HIV and other sexually transmitted infections.

The HIV and hepatitis expert group recommends the introduction of prep in Finland. In this way, new HIV infections can be prevented and the spread of the HIV epidemic can be prevented. Prep treatment would be best organized through public health care. The organizing body should have knowledge of HIV infection, sexually transmitted diseases and

- behavior. The aim of the uniform guidelines is to target medication correctly and to ensure monitoring related to the use of medication. The guidelines are for prep medication based on emtricitabine-tenofovir disoproxil combination therapy.

1 Objectives

Objectives of the national prep guide

- reduce the number of new HIV infections
- reach those at high risk of HIV and other sexually transmitted diseases to find
- and treat undiagnosed cases of HIV and other sexually transmitted diseases
- support the prevention of HIV and other sexually transmitted diseases
- equitable assessment and implementation of prep treatment
-
-
- nationwide monitoring and evaluation.

Prerequisites for achieving the objectives

- treatment is part of public health
- the treatment is affordable or free of charge for the user
- holistic approach to treatment - taking into account e.g. potential need for substance abuse and mental health services

- good knowledge of those implementing prep care about HIV infection, sexually transmitted diseases and behavior, adequate
- awareness of key HIV population groups and health and social care about prep, uniform criteria for starting, monitoring and stopping
- treatment
- nationwide prep care registry.

2 Implementation of treatment

Prep medication can be started by a doctor who is experienced in the treatment of HIV. The doctor assesses the need for prep and monitors the implementation of treatment-related follow-up. Prep treatment should be implemented as part of an HIV prevention strategy, including support for condom use and testing for HIV and other sexually transmitted diseases. In addition, monitoring of the safety of the medicinal product is required. The effectiveness of Prep is based on the use of the medicine in accordance with the instructions, which must be supported and monitored.

Prep is based on the combination of emtricitabine and tenofovir disoproxil. At present, only the original product is in use in Finland. Significantly cheaper generic products will go on sale this spring. However, it is already possible to obtain them with a European prescription from a pharmacy or online pharmacy in another EU or EEA country, prescribed by a Finnish doctor (https://europa.eu/youreurope/citizens/health/prescription-medicine-abroad/prescriptions/index_en.htm # shortcut-2-shkiset-lkemrykset). It is illegal to order medicines from outside the EU.

Prep medicines are not Kela-substitutable, and they do not increase the annual deductible, ie the medicine ceiling. However, the goal is free or affordable care for users. Follow-up of sexually transmitted diseases

(HIV, Chlamydia, smallpox and gonorrhea) research, treatment and medicines are free of charge in public health services (http://www.finlex.fi/fi/laki/ajantasa/1992/19920734).

Prep treatment would be best organized through public health care. The organizer should have knowledge of HIV infection, sexually transmitted diseases and behavior. The aim is to have a uniform assessment of the need for prep treatment and access to treatment. National monitoring and evaluation of treatment would also be easier to implement. On the public side, treatment could be provided primarily by outpatient clinics for infectious and venereal diseases. A national monitoring system should be set up to monitor the efficacy and safety of treatment.

3 Reaching the target group

Prep is for people who are at high risk of getting HIV. Those belonging to vulnerable groups with HIV should receive appropriate and up-to-date information on prep. Here, organizations working on HIV play an important role because they know and reach their target group well.

According to research, most people who benefit from prep recognize the need for prep and apply for prep. However, health and social care must have sufficient information about prep so that people can also be referred from there to assess prep treatment.

4 Indications for treatment

There is indisputable evidence of the effectiveness of Prep in men who have sex between men. Prep should also be considered for other groups if the risk of infection is particularly high. Table 1 shows the high-risk population groups. Table 2 lists the factors that increase the risk of HIV that should be considered when considering prep treatment. However, HIV risk should always be assessed on a case-by-case basis and no one should be categorically excluded from prep. On the other hand, medication should not be started if the person does not have a real high risk of HIV.

When deciding on prep treatment, the suitability of other methods of protection against HIV infection instead of or alongside prep should always be investigated and the need for services that can reduce risk behavior, such as substance abuse and mental health services, sexual counseling or therapy, should be assessed.

Table 1. Population groups at high HIV risk in Finland.

Gay and bim men and other men who have sex between men Injecting drug users
Prisoners
They do sex work
Immigrants at risk of HIV Tourists at increased risk of HIV infection

Table 2. At the individual level, factors that increase the risk of HIV in the previous 12 months.

SEX CONTACTS
Connections without a condom to an HIV-positive person who is not on HIV treatment or who has not achieved a good response to treatment - prep is not necessary during a good response to treatment
Gonorrhea, active syphilis, LGV or rectal Chlamydia
Use of post-exposure prophylaxis (pep) for non-occupational reasons Associations without a
condom with several different people or group sex
Connections without a condom with a person from high-prevalence areas or communities Connections without a condom
with a partner with a high HIV risk
Drug use in sex situations
No possibility to decide on the use of a condom with a sexual partner
INJECTION OF DRUGS
Co-administration of injection equipment with an HIV-positive person who is not on HIV therapy or who has not achieved a good response - prep is not necessary during a good response
Sharing injection equipment abroad or with a person at high risk for HIV

5 Medication

Prep is based on the combination of tenofovir disoproxil-emtricitabine (TDF + FTC, 245 mg / 200 mg). It may be started by a doctor who has experience in the management of HIV (https://pharmacafennica.fi/ spc / 2196744).

Prep can be administered either daily, regardless of the frequency of sexual contact, or as needed in connection with sexual contact. In daily medication, take one tablet once a day at regular intervals. It is recommended that the medicine be taken with food to ensure absorption.

The efficacy of Prep in appropriate use has only been demonstrated in men who have sex between men, and that dosing is not recommended for other groups (Table 3). If necessary, take two tablets at a time 2 to 24 hours before the first exposure and continue to take one tablet daily. Use is discontinued after two days of medication after the last exposure (Figure 1).

All hepatitis B carriers should only take daily medication.

Table 3. Use of prep in different groups.

TDF + FTC	MEN BETWEEN SEX	HETEROSE	TRANSGENDER	DRUG USE BY INJECTION
DAILY MEDICINE	X	X	X	X
NECESSARY MEDICATION	X			

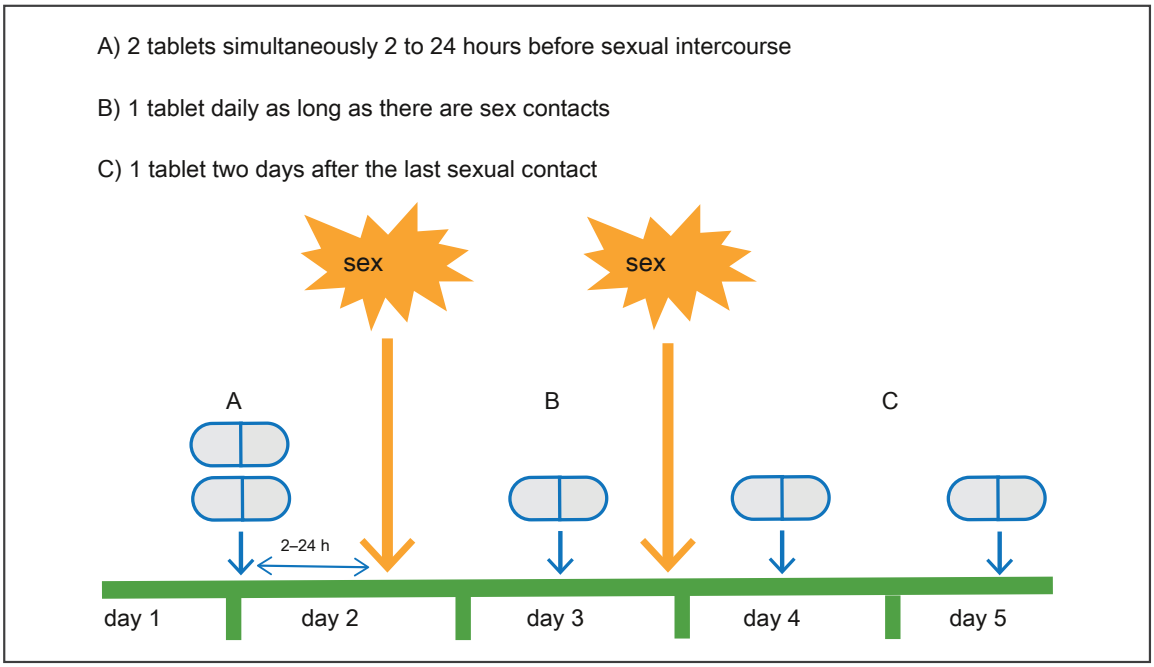

Figure 1. Appropriate medication.

6 Start, follow up and stop

Prep should be offered as part of a package that includes both behavioral and medical means. In connection with Prep, the necessary advice should always be given on the prevention of other sexually transmitted infections and / or blood-borne infections and, if necessary, refer to other services that can reduce the risk of infection.

Using Prep as instructed is of paramount importance for the protection of HIV infection. Commitment to pharmacotherapy must be monitored and supported at each follow-up visit. Measures to support commitment to medication include counseling, training, the use of a dossier and a mobile phone reminder, and carrying spare medicines.

Appropriate laboratory and clinical monitoring should be performed before and during treatment with prep medication. A prep prescription is written for a maximum of three months. A prerequisite for renewing a prescription is that the monitoring is carried out properly.

Medication can be started by a doctor who has experience in the treatment of HIV. The initiation, use, and termination of Prep should follow the written instructions in Tables 4–7 and related. The ICD-10 diagnostic code for receiving a prep visit is Z29.2.

Table 4. Contraindications to initiation.

Positive HIV test result
Symptoms of primary HIV disease - initiation is postponed and HIV status is confirmed 3 months after the last exposure with the S-HIVAgAb test, the HIV nucleic acid test can be used for emergency initiations, P-HIV1Nh
Hypersensitivity to the components of prep drugs and significant interactions of treatment with other drugs Moderate or
severe renal impairment

Renal toxicity and skeletal disorders should also be considered when initiating treatment (https: // pharmacafennica.fi/spc/2196744).

It is a good idea to consult a physician experienced in the treatment of hepatitis B when initiating hepatitis B carrier medication, as prep medication also affects the hepatitis B virus.

Table 5. Discontinuation indications.

Positive HIV test result
Poor adherence to or follow-up of prep medication Reduced risk of HIV
infection
Moderate or severe renal impairment
Hypersensitivity to the components of prep drugs and significant interactions of treatment with other drugs

If HIV infection is detected during prep treatment, an area infection physician should be consulted immediately. Discontinuation of medication should also be considered in association with nephrotoxic drugs and skeletal disorders. Discontinuation of hepatitis B carrier medication should be discussed with the physician responsible for hepatitis monitoring, as discontinuation of the prep may result in hepatitis activation.

Table 6. Start and end times.

	START	END
DAILY MEDICINE	• 7 days before exposure	• 7 days after last exposure
APPROPRIATE MEDICINE (FIGURE 1)	• two tablets at the same time 2 to 24 hours before exposure	• two days after the last exposure (1 tablet / day)

Table 7. Monitoring before start, during operation, and during interruption or termination.

LABORATORY MONITORING	BEFORE GETTING STARTED	30 VRK GETTING STARTED	3 MONTHS GETTING STARTED AND HERE EVERY 3 MONTHS	12 KK AND HERE EVERY 12 MONTHS	3 MONTHS OR END AFTER
HIV • S-HIV AgAb - laboratory test for vascular blood *	X	X	X		X
SYPHILIS • S-TrpaAb - previously treated syphilis cases of S-KardAb and S-TPHA	X		X		X
KLAMYDIA AND TYPPIR • CtGcNhO - sample and urine, from the pharynx to the anus **	X		X		X
HEPATITIS A • S-HAVAb - vaccination is recommended in the absence of protection	X				
HEPATITIS C *** • S-HCVAb - Follow-up of HCV-treated patients is performed by PCR assay S-HCVNhO or S-HCVNh	X			X	
HEPATITIS B STUDIES • S-HBsAg, S-HBcAb, S-HBsAb - vaccination is recommended in the absence of protection - HBsAg positive is recommended daily prep dosing only	X			X (if the person does not no protection)	
CREA (eGFR)	X		X ****		
U-PROTEIN (U-prot or U-prot-O)	X				
PREGNANCY TEST	X				

OTHER MONITORING	BEFORE GETTING STARTED	30 VRK GETTING STARTED	3 MONTHS GETTING STARTED AND HERE EVERY 3 MONTHS	12 KK AND HERE EVERY 12 MONTHS	3 MONTHS OR END AFTER
Prep need assessment	X	X	X		
Acute HIV disease exploring the possibility	X	X	X		
Prepine commitment ensuring	X	X	X		
Counseling for other sexually transmitted and / or blood-borne diseases protection (condoms, clean injection instruments)	X	X	X		
Mental health and addiction problem solving and care guidance	X	X	X		

* Testing should be done on vascular blood by a laboratory test, S-HIVAbAg. Rapid and home tests usually do not contain an Ag component.

* * In addition to the chlamydia and gonorrhea urine sample, a sample must be taken from the throat if there has been oral sex and from the anus if there has been anal sex

* * * Hepatitis C testing every three to six months is recommended if the person is actively using injecting drugs, including chemsex.

* * * * If the values are normal, the follow-up interval can be increased to 6 months.

The recommended follow-up visit is 30 days from the start of the prep, the next 3 months from the start of the prep, and every 3 months thereafter. The need for Prep must be assessed before starting medication and at each follow-up visit. In addition, the need for services related to a person's mental health and addictions that could reduce risky behavior and / or support prep commitment should be identified. Each visit should remind you to use a condom to prevent other sexually transmitted diseases.

Undiagnosed HIV infections are often common in populations for which prep is recommended. Prep medication in an HIV-infected person can lead to the emergence of drug-resistant virus strains and the spread of infection. As a result, a person's HIV status must be determined before starting prep medication using the HIVAgAb test (a laboratory test for blood vessels, not a home or rapid test). If acute HIV infection is suspected, the HIVAgAb test should be repeated 3 months after the last exposure before starting prep, or HIV1Nh nucleic acid testing may be considered if initiation of prep is urgent (note: HIV1Nh test does not detect HIV-2 infections). The start of medication should be delayed until the result is obtained.

The HivAgAb test is maintained at each follow-up visit. Follow-up visits must also be used to find out whether a person has the possibility of an acute HIV disease. If acute HIV infection is suspected during prep therapy, both HIVAgAb and a nucleic acid test, HIV1Nh, should be performed. Prep medication may continue pending the outcome of these, but risk behaviors should be avoided. In a recent HIV infection, there is a considerably high risk of passing HIV on.

Hepatitis A, B, and C antibodies and hepatitis B carrier (HbsAg) should be determined before initiating therapy. Hepatitis A and B vaccination is recommended if a person is not protected against these diseases. Both hepatitis A and B vaccines are available free of charge in public health, including injecting drug users, their loved ones, such as family members, sexual partners and partners, and men who have sex with men. A combination vaccine for hepatitis A and B can be used for vaccination if the person is not immune to either virus. In addition to the above, the hepatitis B vaccine is available free of charge to the sexual partners of the carriers of hepatitis B infection and to those living in the same household and sex workers. More detailed vaccination instructions can be found on THL's Vaccination website. (https://thl.fi/fi/web/rokottaminen). Serological testing for hepatitis B and C should be performed every 12 months in individuals without hepatitis B or C infection or hepatitis B vaccine protection. Hepatitis C testing every three months is recommended if the person has active injecting drug use, including chemsex. If the person has received hepatitis C treatment, testing should be performed by PCR.

Previously undiagnosed hepatitis B and / or C positive individuals should be referred to a physician experienced in the treatment of these infections. TDF + FTC is also effective against hepatitis B. For hepatitis B carriers, daily use of prep is only recommended, not as needed. Hepatitis B and C positive individuals should be monitored for hepatitis according to standard practice. When considering discontinuation or discontinuation of prep therapy, the patient's need for hepatitis B therapy should be evaluated. Discontinuation may lead to exacerbation of hepatitis B infection.

Chlamydia, gonorrhea and syphilis testing should be performed before starting treatment and every three months thereafter. A urine sample alone is not sufficient to detect chlamydial and gonorrhea infections of the pharynx and anus. If the person has had oral or anal sex, chlamydia and gonorrhea testing should be performed not only on urine but also on a sample taken from the throat and / or anus.

Renal function should be checked before starting prep and that other medicines used by the person should not interact with prep medicines (www.hiv-druginteractions.org).

The initiation, continuation and monitoring of the use of Prep should be considered with special care if the person has kidney disease or is taking nephrotoxic drugs or skeletal disease.

A pregnancy test should be performed on all women of childbearing potential before starting prep therapy. The benefits and risks of Prep should be discussed if a person wants to use Prep during pregnancy or breastfeeding. Pregnancy does not require termination of the prep if the person is still at high risk of contracting HIV. The medication protects both pregnant and unborn babies from HIV infection.

When prescribing or stopping Prep, the time limits in Table 6 and possible exacerbation of hepatitis B infection should be considered.

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