

Olu xwebhu lunikeza ushwankathelo olufutshane lolu phononongo kuluntu jikelele. Ungafumana inkcazelo engakumbi kushwankathelo lwezenzululwazi lophononongo. Ilinki eya kushwankathelo ifumaneka ekupheleni kolu xwebhu.

Amagama ophononongo

Isihloko Esifutshane: Uphononongo lokufunda malunga neempembelelo kunye nokhuseleko lwe-dolutegravir ne-lamivudine kubathathi-nxaxheba abaneminyaka esuka kwi-12 ukuya ngaphantsi kwe-18 ubudala abasanda kufunyaniswa bene-HIV.

Isihloko Sezenzululwazi Esipheleleyo: Uphononongo olulibonisayo iyeza, oluneqela elinye lonyango ukuze kuhlolwe ukusebenza nokukhuseleka kwamachiza amabini i-dolutegravir/lamivudine (DTG/3TC) kwiveki yama-48 njengamathamo adityanisiweyo angatshintshiyo (iFixed Dose Combination - i-FDC), kwabafikisayo abane-HIV-1 abangazange balufumana unyango lwe-antiretroviral (i-ART), nabaneminyaka ukusuka kweli-12 ukuya kutsho ngaphantsi kweli-18 ubudala nabanobunzima bomzimba obungama-25 kg ubuncinane.

Inombolo Yophononongo ye-ViiV Healthcare: 205861

Ngubani oxhase olu phononongo?

I-ViiV Healthcare

Idesika Yoncedo Yenxaso Yezonyango yakwa-GSK

Iwebhusayithi: clinicalsupporthd.gsk.com/contact.html

I-imeyile: GSKClinicalSupportHD@gsk.com

Inkcazelo jikelele malunga nophononongo lwezonyango

Lwenziwe nini olu phononongo?

Uphononongo luqalise ngo-Apreli 2019. Ukubhalisa bekuvaliwe, kodwa uphononongo belusaqhubeka ngoxa bekugqitywa ukwenziwa olu shwankathelo.

Ukusetyenziswa kwengcombolo nenkcazelo equlethwe kolu Xwebhu akumiselwanga mda, kuphela ukuba ayizukusetyenziswa kwizicelo ngabanye ukuze kuvunywe ngokusemthethweni imveliso. Nangona kungeyomfuneko, xa usebenzisa le ngcombolo, sicela ukuba abakwa-ViiV Healthcare banikwe iwonga okanye imfanelo njengomthombo wengcombolo. Abakwa-ViiV Healthcare/GSK bayala ukwamkela ityala lokusetyenziswa kwengcombolo yolu Xwebhu ngabasebenzisi, ngokomkhamo opheleleyo ovunyelwa ngumthetho osebenzayo. Akukho phawu lorhwebo, lungelo lokuthengisa, okanye malungelo okusebenzisa yedwa ulawulo/iingcombolo abanjwe ngabakwa-ViiV Healthcare/GSK ahanjisiweyo, akhutshelwe ngemphepha-mvume okanye achatshazelwayo nangayiphi indlela.

Ibiyintoni injongo ephambili yolu phononongo?

Intsholongwane ebulala amajoni omzimba yoHlobo 1 (HIV) yonakalisa inkqubo yamajoni omzimba. Yenza umzimba ungakwazi ukulwa nolosuleleko kwaye yandisa umngcipheko wokuqalwa zizifo xa inganyangwa kakuhle. Oogqirha bangahlola umlinganiselo we-HIV esemzimbeni (inani lentsholongwane esegazini) ngokulinganisela izinto zemfuza ekuthiwa ngamaqondo eribonucleic acid (i-RNA) ye-HIV egazini.

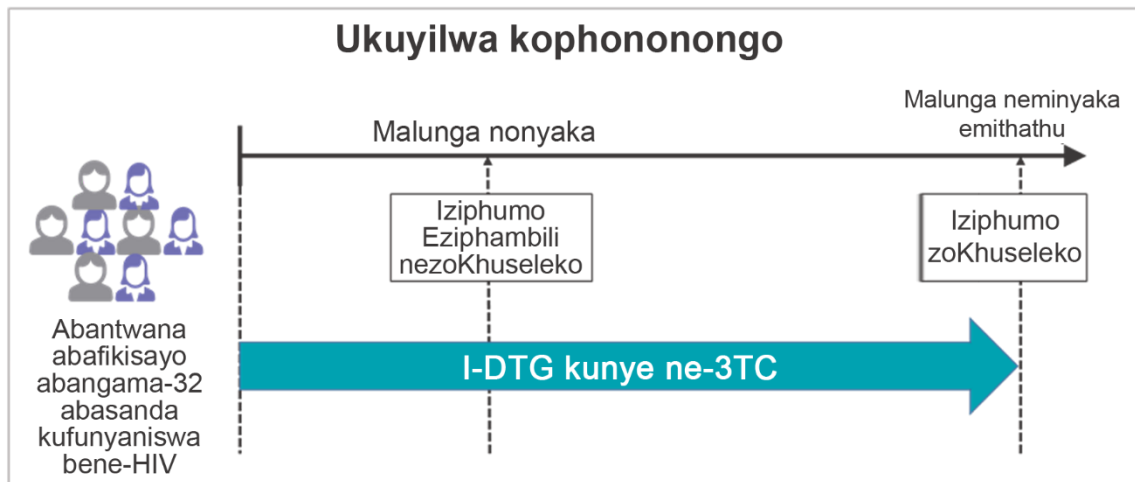
Amayeza e-HIV alawula inani lentsholongwane esegazini ngokuyithintela ingavelisi naziphi na iintsholongwane ezongezelelekileyo. Abaphandi bathatha ukuba la mayeza asebenza kakuhle ukuba inani lentsholongwane esegazini labathathi-nxaxheba lingaphantsi kweekopi ezingama-50 kwimililitha [c/mL] yegazi). Oku kuthetha ukuba amaqondo e-HIV asegazini akabonakali. La maqondo athathwa ngokuba aphantsi kakhulu ukuba angonzakalisa amajoni omzimba kwaye aqhele ukuvavanywa ezikliniki ukuhlola isimo se-HIV somthathi-nxaxheba.

Ipilisi eyindibanisela eyenzelwe i-HIV ivunyiwe kumazwe aliqela ukuze inyange abantu abadala abaphila ne-HIV. Ngabantwana abafikisayo (abaneminyaka eli-12 ukuya ngaphantsi kweli-18 ubudala) abasanda kufunyaniswa bene-HIV nabangekafumani unyango lwe-HIV abathathe inxaxheba kolu phononongo. Abaphandi bebefuna ukubona ukuba ingaba le ndibanisela inye yale pilisi ingayinciphisa na okanye iyigcine na ingabonakali imilinganiselo yentsholongwane kwaba bathathi-nxaxheba. Bakwaphonononge nokhuseleko lwala mayeza baza bathelekisa iziphumo ezivela kolu phononongo neziphumo ezivela kuphononongo lwangaphambili kubantu abadala abaphila ne-HIV.

Ngawaphi amayeza aye aphononongwa?

Ipilisi eyindibanisela yamayeza e-HIV i-dolutegravir (i-DTG) ne-lamivudine (i-3TC) iye yaphononongwa.

Olu luphononongo olulibonisayo iyeza apho abathathi-nxaxheba kunye nogqirha wabo wophononongo bebesazi ukuba umthathi-nxaxheba ufumana oluphi unyango. Ukusukela ngoSuku 1, bonke abathathi-nxaxheba kolu phononongo bafumene ipilisi eyindibanisela ye-DTG ne-3TC kanye ngosuku njengoko kubonisiwe kumfanekiso ongezantsi.



Abathathi-nxaxheba abagqibe iminyaka emithathu yonyango (ngeVeki 144) bebenokuqhubeka neyeza lophononongo de lifumane ugunyaziso kwaye lifumaneke kwilizwe labo.

Ngabaphi abathathi-nxaxheba abebequkwe kolu phononongo?

Uphononongo lunoluhlu lweemfuneko lwabathathi-nxaxheba abanokubhalisa (imfuneko yokuqukwa) nabo bangenakho (imfuneko yokungaqukwa). Kolu phononongo, imfuneko yokuqukwa nokungaqukwa ephambili idweliswe ngezantsi.



Amakhwenkwe namantombazana ane-HIV aye aba yinxalenye yolu phononongo ukuba:

- Bebeneminyaka eli-12 ukuya kwengaphantsi kwe-18 ubudala.
- Bebenobunzima bomzimba ofikileyo kwi-25 kilogram ubuncinane.
- Bebenenani lentsholongwane esegazini eliphakathi ko-1000 kunye no-500,000 c/mL ngaphambi kokuba bangene kuphononongo.
- Bebegazange bathathe amayeza e-HIV ngaphambili.

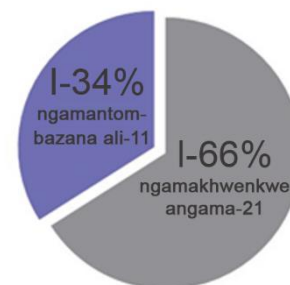


Amakhwenkwe namantombazana khangе babe yinxalenye yolu phononongo ukuba:

- Bebexhathisa (iyeza alisasebenzi) kwi-DTG, i-3TC, okanye kumayeza ayeleleneyo.
- Nasiphi esinye isi(zi)fo, iziphumo ezingaqhelekanga zovavanyo lwegazi, okanye uthathe naliphi i(ama)yeza athi ugqirha wophononongo acinge ukuba lingachaphazela iziphumo zophononongo.

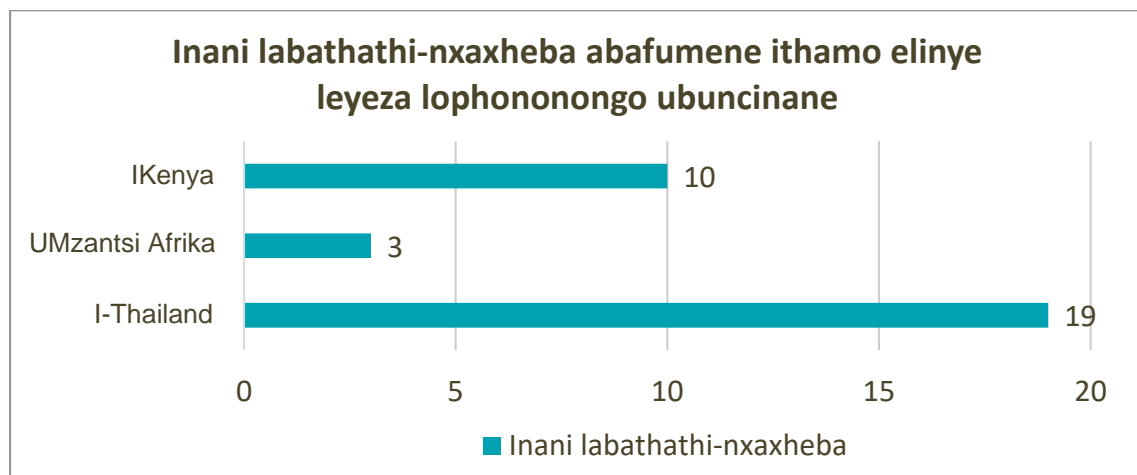
Bebonke, ngabathathi-nxaxheba abayi-32 abafumene ithamo elinye leyeza lophononongo ubuncinane. Umyinge weminyaka yobudala ubuyiminyaka eyi-16. Oyena mthathi-nxaxheba umncinane ebeneminyaka eyi-13 ubudala kwaye oyena mthathi-nxaxheba umdala ebeneminyaka eyi-17 ubudala.

Isini saBathathi-nxaxheba



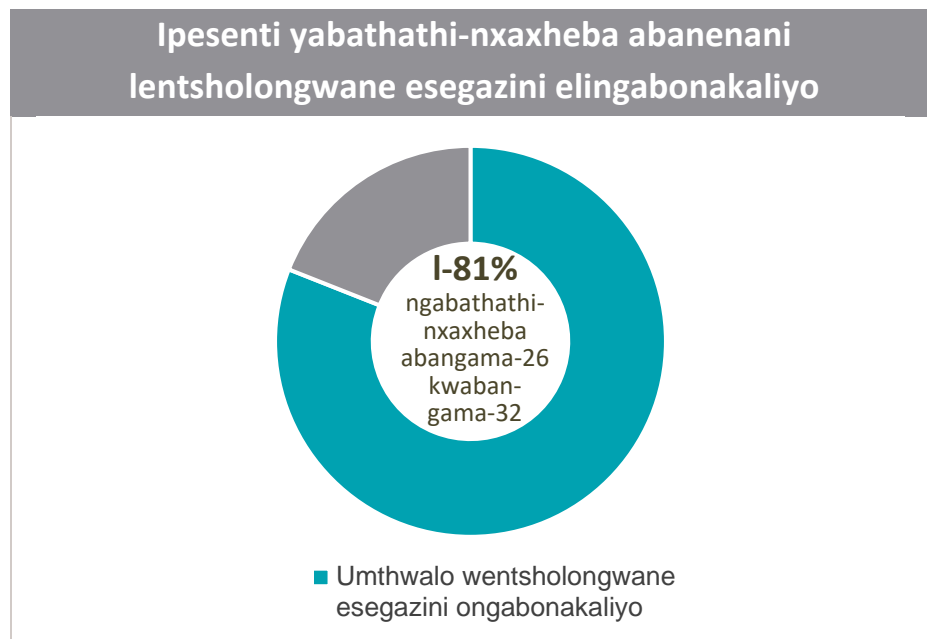
Lwenziwe phi olu phononongo?

Iziza zophononongo bezikumazwe ama-3.



Bezisithini iziphumo eziphambili zolu phononongo?

Oogqirha bophononongo baqokelele iisampuli zegazi kwaye balinganisele amanani entsholongwane esegazini labathathi-nxaxheba. Abaphandi bahlole ipesenti yabathathi-nxaxheba abanenani lentsholongwane esegazini elingabonakaliyo (elingaphantsi kwe-50 c/mL) emva kwesithuba esimalunga nonyaka (ngeVeki 48).



Bekukho abathathi-nxaxheba abathathu abanenani lentsholongwane esegazini elibonakalayo kunye nabathathi-nxaxheba abaphumileyo kuphononongo ngaphambi kotyelelo lweVeki 48.

Bizeziphi iziphumo ezingathandekiyo?

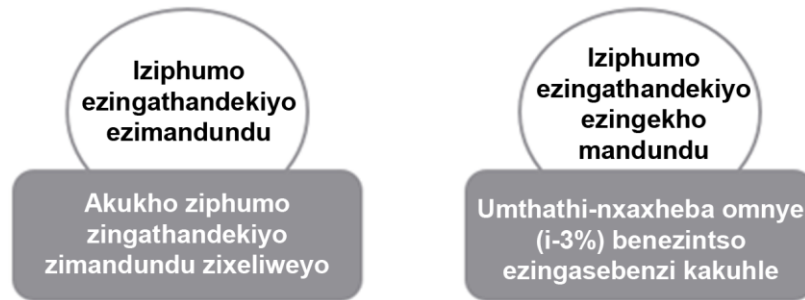
Iziganeko zonyango ezingafunwayo (iziganeko ezimandundu) zingenzeka kubantu xa befumana iyeza. Oogqirha bophononongo bazibhala phantsi ezi ziganeko. Kolu shwankathelo, **iziphumo ezingathandekiyo** zibhekisela kwezo ziganeko ugqirha wophononongo acinga ukuba zibangelwe liyeza lophononongo.

Iziphumo ezingathandekiyo kolu shwankathelo zisenokwahluka kwezo zifumaneka Kwimvume Yowazisiweyo okanye kwamanye amaxwebhu anxulumene neyeza lophononongo. Isishwankathelo sazo zonke iziganeko ezixelwe kolu phononongo singafunyanwa kwisishwankathelo seziphumo zezonyango.

Iziphumo ezingathandekiyo ezikwesi sishwankathelo ziye zaxelwa ukususela kuSuku 1 ukuya kwisithuba esimalunga nonyaka (kwiVeki 48).

Akukho mthathi-nxaxheba ubhubhileyo ngexesha lophononongo.

Inani labathathi-nxaxheba abaneziphumo ezingathandekiyo



Olu phononongo lubancede njani abathathi-nxaxheba kunye nabaphandi?

Abaphandi baqokubele ngelithi, ipilisi eyindibanisela ye-DTG ne-3TC basabele ngokuyeleleneyo ekuthotyweni nasekugcinweni kwenani lentsholongwane esegazini labantwana abafikisayo abasanda kufunyaniswa bene-HIV xa kuthelekiswa nabantu abadala abaphila ne-HIV. Isiphumo esingathandekiyo esingekho mandundu esixelwe kolu phononongo ibe seso silindelekileyo.

Ingaba kukho izicwangciso zophononongo olungakumbi?

Olunye uphononongo lwe-DTG kunye ne-3TC kubantu abadala abaphila ne-HIV sele lugqityiwe. Olunye luyaqhubeka okanye lucwangcisiwe. Akukho phononongo lulolunye lwe-DTG ne-3TC kubantwana abafikisayo abasanda kufunyaniswa bene-HIV lucwangcisiweyo okwangoku.

Ndingayifumana phi inkcazelo engakumbi malunga nolu phononongo?

Uphononongo lwezonyango luneenombolo zophononongo ezikhethekileyo. Inombolo yophononongo ekhethekileyo enxulumene nolu phononongo iboniswa ngezantsi kunye nelinki ye-intanethi eya kushwankathelo lwezenzulwazi.

Umbutho (iWebhusayithi)	Isiphawuli soPhononongo
I-United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	NCT03682848 ¹

¹<https://clinicaltrials.gov/ct2/show/NCT03682848>

Ushwankathelo lwezenzululwazi luquka iinkcukacha ezingakumbi malunga neemfuneko zokubhaliswa kuphononongo, ucwangciso lotyelelo lophononongo, iziphumo ezisuka kwamanye amanqanaba okugqibela nenkcazelo eneenkcukacha ezingakumbi malunga neziganeko ezimandundu. Xa uphononongo lugqityiwe, iziphumo zokugqibela ziya kufumaneka kwisishwankathelo sezenzululwazi.

Ugqirha wakho angakunceda uqonde ngakumbi olu phononongo kunye neziphumo. Awufanele wenze utshintsho kunakekelo lwakho ngokusekelwe kwiziphumo zolu phononongo okanye naluphi na olunye uphononongo.

Singathanda **ukubulela abathathi-nxaxheba** abafake isandla kolu phononongo. Iziphumo zolu phononongo ziza kunceda ukuphendula imibuzo yezenzululwazi ngokunyanga abantwana abafikisayo abasanda kufunyaniswa bene-HIV.

Isiqulatho solu xwebhu siye sagqityezelwa ngabakwa-ViiV Healthcare nge-31 kaMeyi 2022. Inkcazelo ekolu shwankathelo ayiquki inkcazelo eyongezelelekileyo efumaneka emva kwalo mhla.