Isifinyezo Semiphumela Yocwaningo Lwezokwelapha

Ucwaningo oluhlola ukuphepha kwe-baloxavir marboxil ezinganeni ezinemfuluwenza ezingaphansi konyaka o-1 (miniSTONE-1)

Buka ekupheleni kwesifinyezo ukuze ubone isihloko esiphelele socwaningo.

Mayelana nalesi sifushaniso

Lesi isifinyezo semiphumela yocwaningo lwezokwelapha (olubizwa ngokuthi 'ucwaningo' kule dokhomenti) – esibhalelwe:

- amalunga omphakathi, kanye
- nabantu ababamba iqhaza ocwaningweni

Lesi sifinyezo sisekelwe olwazini obelukhona ngesikhathi sokubhala.

Ucwaningo lwaqala ngoJanuwari 2019 lwase luphela ngoJulayi 2023. Lesi sifinyezo sabhalwa ngemva kokuba ucwaningo seluphelile.

Alukho ucwaningo olulodwa olungasitshela yonke into ngezingozi nezinzuzo zomuthi. Kudinga abantu abaningi abasocwaningweni oluningi ukuze kutholakale konke esidinga ukukwazi. Imiphumela evela kulolu cwaningo ingase ihluke kwezinye izingcwaningo ezenziwa ngomuthi ofanayo.

- **Lokhu kusho ukuthi akufanele wenze izinqumo ezisekelwe kulesi sifinyezo esisodwa – njalo khuluma nodokotela wakho ngaphambi kokwenza noma yiziphi izinqumo mayelana nokwelashwa kwengane yakho**

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3. Yini eyenzekile phakathi nalolu cwaningo?
4. Yayithini imiphumela yocwaningo?
5. Lolu cwaningo lulusize kanjani ucwaningo?
6. Ingabe zikhona izinhlelo zezinye izingcwaningo?
7. Ngingalutholaphi ulwazi olwengeziwe?

Siyabonga kubantu ababambe iqhaza kulolu cwaningo

Abantu ababamba iqhaza baye basiza abacwaningi ukuba baphendule imibuzo ebalulekile mayelana nemfuluwenza nomuthi ocwaningwayo (i-baloxavir marboxil), ongase ube nezinzuzo kuwo wonke umphakathi.

Ulwazi olubalulekile mayelana nalolu cwaningo

- Lolu cwaningo lwenzelwa ukubona ukuthi i-baloxavir marboxil iphephile yini ukuba isetshenziswe ezinganeni ezingaphansi konyaka o-1
- Lolu cwaningo lwaluhlanganise izingane ezingama-48 emazweni ayi-7 (i-Costa Rica, Finland, Mexico, Poland, Ningizimu Afrika, Spain ne-USA)
- Umphumela oyinhloko waba ukuthi i-baloxavir marboxil iphephile ukuba izingane ezingaphansi konyaka o-1 ziyithathe njengoba nje iphephile ezinganeni esezikhulile nakubantu abadala
- Azikho ezinganeni ezabamba iqhaza ezaba nemithelela engemihle emibi kakhulu eyayihlobene ne-baloxavir marboxil

1. Ulwazi oluvamile mayelana nalolu cwaningo

Kungani lwenziwa lolu cwaningo?

Imfuluwenza, ebizwa futhi ngokuthi i-flu, iyisifo esivamile esibangwa ukutheleleka ngegciwane le-flu. Izimpawu ezivamile zihlanganisa imfiva, ukukhwehlela, umphimbo obuhlungu, ubuhlungu bomzimba nokukhathala.

Abantu abaningi bayalulama kwi-flu phakathi nesonto ngaphandle kokuba badinge ukubona udokotela. Ngezinye izikhathi, i-flu ingaholela ekuguleni (izinkinga) okubi ngokwengeziwe njengokuvuvukala kwamaphaphu (inyumoniya) noma ubuthi egazini (i-sepsis). I-flu ngokuvamile iphatha izingane, futhi zisethubeni elikhulu kunabantu abadala lokuba zibe nezinkinga.

Kunemithi eminingi ongazithengela yona engasetshenziswa ekwelapheni izimpawu ze-flu, kodwa aziyelaphi imbangela – ukutheleleka ngegciwane. Imithi ihlasela igciwane le-flu ngokuqondile. Ingatholakala ngencwadi kadokotela noma kusokhemisi. Unyaka ngamunye, izigidi zabantu emhlabeni wonke zidinga ukwelashelwa i-flu.

I-baloxavir marboxil iwumuthi wemfuluwenza osebenza ngokwehlukile kweminye imithi ehlasela amagciwane. Ibonakale isebenza ekwelapheni i-flu kubantu abadala nasezinganeni okungenani ezinonyaka o-1 ubudala. Lolu cwaningo lwahlola indlela i-baloxavir marboxil ephephe ngayo ezinganeni ezingaphansi konyaka o-1 ubudala.

Bekuyini umuthi wocwaningo?

Lolu cwaningo lwalugxile emuthini obizwa ngokuthi i-'baloxavir marboxil'.

- Leli gama ulibiza ngale ndlela 'ba-lox-av-ear mar-box-il'
- I-baloxavir marboxil isebenza ngokuvimba igciwane le-flu ekuziphindaphindeni emzimbeni
- Lokhu kungase kusho ukuthi i-flu ayibi yimbi kangako futhi izingane zilulama ngokushesha ngokwengeziwe lapho zelashwa nge-baloxavir marboxil

Yini ababefuna ukuyithola abacwaningi?

Nangu umbuzo oyinhloko abacwaningi ababefuna ukuwuphendula:

Zingaki izingane ezibe nemithelela engemihle (izinkinga zokwelapha ezenzeka phakathi nocwaningo) ngenxa yokwelashwa nge-baloxavir marboxil?

Bekuwuhlobo olunjani locwaningo lolu?

Lolu bekuwucwaningo 'lweSigaba 3'. Lokhu kusho ukuthi lwelula ucwaningo lwangaphambilini ukuze luthole mayelana nemithelela engemihle ye-baloxavir marboxil ezinganeni ezingaphansi konyaka o-1 ubudala. Sekunganqunywa-ke ukuthi umuthi ungagunyazwa yini ukuba odokotela bawunikeze izingane ezisencane kakhulu.

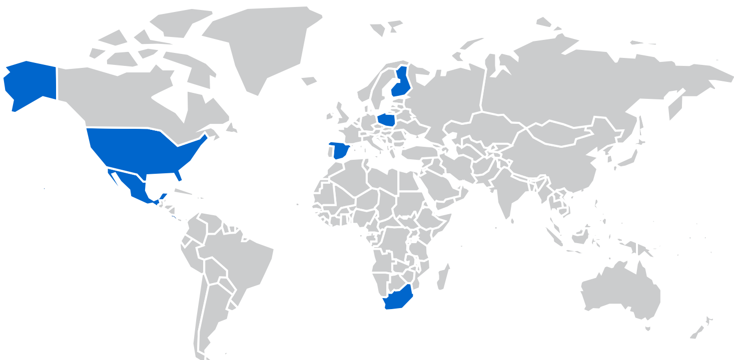
Lolu bekuwucwaningo 'lwelebula evulekile'. Lokhu kusho ukuthi kokubili abantu ababebamba iqhaza ocwaningweni nodokotela bocwaningo babewazi umuthi owawunikezwe izingane.

Lolu cwaningo lwenzeke nini futhi kuphi?

Ucwaningo lwaqala ngoJanuwari 2019 lwase luphela ngoJulayi 2023. Lesi sifinyezo sabhalwa ngemva kokuba ucwaningo seluphelile.

Ucwaningo lwenziwa ezikhungweni zocwaningo eziyi-15 emazweni ayi-7 aboniswe ebalazweni elilandelayo:

- Costa Rica
- Finland
- Mexico
- Poland
- ENingizimu Afrika
- Spain
- USA

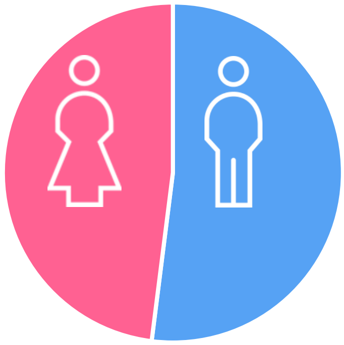


2. Ubani obamba iqhaza kulolu cwaningo?

Kulolu cwaningo, izingane ezingama-48 ezingaphansi konyaka o-1 ubudala ezazitheleleke nge-flu noma ngezimpawu ezinjengeze-flu zabamba iqhaza.

48%

Izingane ezingama-23 kwezingama-48 ezabamba iqhaza



52%

Izingane ezingama-25 kwezingama-48 ezabamba iqhaza

Iminyaka yobudala: ngaphansi konyaka o-1 ubudala

- Zazinomphumela olandula ubukhona begciwane lapho kuhlolwa i-COVID-19 phakathi nezinsuku ezi-2 zokubona udokotela
- Zabona udokotela phakathi nezinsuku ezi-4 zokuba nezimpawu ze-flu

Izingane bezingeke zibambe iqhaza kulolu cwaningo uma:

- Zazidinga ukwelashelwa i-flu (noma okunye ukugula) esibhedlela
- Zazinikezwe omunye umuthi owawungaphazamisa indlela i-baloxavir marboxil esebenza ngayo
- Zazizalwe ngaphambi kwesikhathi, noma zazinesisindo esingaphansi kuka-2.5kg

3. Yini eyenzekile phakathi nalolu cwaningo?

Phakathi nocwaningo, zonke izingane ezazibambe iqhaza zanikezwa umthamo owodwa we-baloxavir marboxil uyizinhlayiya eziphuzwayo zixutshwe namanzi. Umthamo owanikezwa wawuncike esisindweni sazo somzimba.

Lapho ucwaningo luphela, abazali noma abanakekeli bezingane ezazibamba iqhaza bacelwa ukuba babuyele esikhungweni sabo socwaningo ekuvakasheni okwengeziwe – ukuze kuhlolwe impilo yalezi zingane iyonke. Bheka ngezansi ukuze ubone imininingwane eyengeziwe mayelana nalokho okwenzeka ocwaningweni.

Ukukhethwa kwezingane ezazizobamba iqhaza ocwaningweni → **Izingane ezingama-48 zanikezwa umthamo owodwa we-baloxavir marboxil** → **Odokotela baqhubeka nokuhlola impilo yezingane ezabamba iqhaza, kwaze wafika ezinsukwini**

4. Yayithini imiphumela yocwaningo?

Umbuzo oyinhloko: Zingaki izingane ezaba nemithelela engemihle ngenxa yokwelashwa nge-baloxavir marboxil?

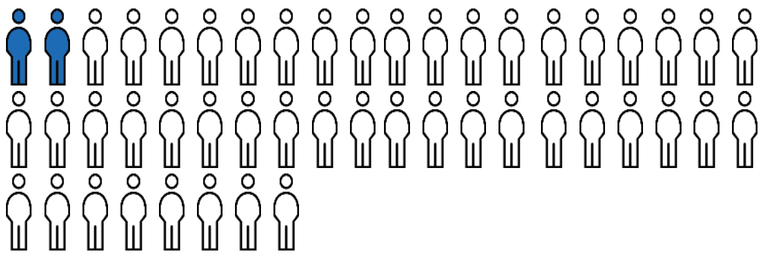
Imithelela engemihle iyizinkinga zokwelapha ezenzeka phakathi nocwaningo.

Imithelela engemibi kakhulu iyizinkinga zokwelapha (njengokuzizwa unenzululwane) phakathi nocwaningo. Imithelela emibi kakhulu yileyo ebanga ukulaliswa esibhedlela okungahleliwe (noma ukulaliswa esibhedlela isikhathi eside kunesihleliwe) noma esongela ukuphila, ebanga ukukhubazeka kwesikhathi eside noma ukufa. Kwaboniswa kuphela imithelela engemihle odokotela abacabanga ukuthi yayihlobene nomuthi wocwaningo.

Akuzona zonke izingane kulolu cwaningo ezibe nemithelela engemihle.

Azikho ezaba nemithelela emibi kakhulu eyayihlobene nomuthi wocwaningo ezinganeni ezabamba iqhaza kulolu cwaningo.

Ezinganeni ezingama-48 ezazikulolu cwaningo, ezi-2 (4%) zaba nemithelela engemibi kakhulu okwacatshangwa ukuthi yayihlobene nomuthi. Yomibili le mithelela engemihle yayiwuhudo.



Izingane ezi-2 kwezingama-48 zazinemithelela engemibi kakhulu okwacatshangwa ukuthi yayihlobene nomuthi

Phakathi nocwaningo, ezinganeni ezelashwa nge-baloxavir marboxil azikho ezafa ngenxa yemithelela engemihle okungenzeka ukuthi yayihlobene nomuthi wocwaningo.

Ezinganeni ezelashwa nge-baloxavir marboxil azikho ezayeka ukunikezwa umuthi wocwaningo ngenxa yemithelela engemihle.

Le ngxenye ibonisa kuphela imiphumela eyinhloko evela kulolu cwaningo. Ungathola ulwazi olwengeziwe mayelana nemiphumela yocwaningo kumawebhusayithi ekupheleni kwalesi sifinyezo (bheka iNgxenye 7.

5. Lolu cwaningo lulusize kanjani ucwaningo?

Ulwazi olunikezwe lapha luvela ocwaningweni olulodwa lwezingane ezingama-48 ezingaphansi konyaka o-1 ubudala ezazine-flu. Le miphumela yasiza abacwaningi bafunda okwengeziwe nge-flu ne-baloxavir marboxil, okwakungaholela ekwelashweni kangcono komphakathi wonkana.

Imiphumela eyinhloko yocwaningo iwukuthi i-baloxavir marboxil ngokuvamile iphephile ezinganeni ezingaphansi konyaka o-1 ubudala futhi ayizange ibe khona imithelela emibi kakhulu eyayihlobene nomuthi. Lokhu kuyavumelana nokuphepha okwaziwayo kwe-baloxavir marboxil ezinganeni esezikhulile, entsheni nakubantu abadala.

Alukho ucwaningo olulodwa olungasitshela yonke into ngezingozi nezinzuzo zomuthi. Kudinga abantu abaningi abasocwaningweni oluningi ukuze kutholakale konke esidinga ukukwazi. Imiphumela evela kulolu cwaningo ingase ihluke kwezinye izingcwaningo ezenziwa ngomuthi ofanayo.

- **Lokhu kusho ukuthi akufanele wenze izinqumo ezisekelwe kulesi sifinyezo esisodwa – njalo khuluma nodokotela wakho ngaphambi kokwenza noma yiziphi izinqumo mayelana nokwelashwa kwengane yakho.**

6. Ingabe zikhona izinhlelo zolunye ucwaningo ezinganeni?

Ucwaningo lwe-baloxavir marboxil lusaqhubeka.

I-CENTERSTONE iwucwaningo oluhlola umthelela we-baloxavir marboxil ekuvimbeni ukusabalala kwe-flu kubantu abaneminyaka emi-5 kuya kwengama-64 ubudala.

I-PEBBLESTONE iwucwaningo lwe-baloxavir marboxil ezinganeni ezinonyaka o-1 kuya ku-11 ubudala, oluhlola inkani yegciwane lemfuluwenza, okuyilapho kwenzeka izinguquko ngaphakathi kwegciwane okungenza umuthi wegciwane ungasebenzi kahle.

Imininingwane eyengeziwe mayelana nalolu cwaningo ingatholakala lapha:

- https://clinicaltrials.gov/study/NCT03969212
- https://clinicaltrials.gov/ct2/show/NCT06094010

7. Ngingalutholaphi ulwazi olwengeziwe?

Ungathola ulwazi olwengeziwe mayelana nalolu cwaningo (miniSTONE-1) kumawebhusayithi abhalwe ngezansi:

- https://clinicaltrials.gov/ct2/show/results/NCT03653364
- https://www.clinicaltrialsregister.eu/ctr-search/trial/2018-002154-70/FI
- https://forpatients.roche.com/ en/trials/infectious-diseases/influenza/study-to-assess-the-safety--pharmacokinetics--and-effic-62594.html

Ubani engingaxhumana naye uma nginemibuzo mayelana nalolu cwaningo?

Uma uneminye imibuzo ngemva kokufunda lesi sifushaniso:

- Vakashela inkundla ye-ForPatients bese ugcwalisa ifomu lokuxhumana – https://forpatients.roche.com/ en/trials/infectious-diseases/influenza/study-to-assess-the-safety--pharmacokinetics--and-effic-62594.html
- Xhumana nommeleli ehhovisi leRoche ezweni lakini.

Uma ingane yakho ike yabamba iqhaza kulolu cwaningo futhi unemibuzo mayelana nemiphumela:

- Khuluma nodokotela wakho wocwaningo

Uma unemibuzo mayelana nokwelashwa kwengane yakho:

- Khuluma nodokotela ophethe ukwelashwa kwengane yakho.

Ubani owahlela futhi wakhokhela lolu cwaningo?

Lolu cwaningo lwahlelwa futhi lwakhokhelwa yi-F. Hoffmann-La Roche Ltd, enekomkhulu e-Basel, Switzerland.

Isihloko esigcwele socwaningo nolunye ulwazi oluluhlonzayo

Isihloko esiphelele salolu cwaningo sithi: "Ucwaningo Lokuhlola Ukuphepha, Ukuhamba Komuthi Emzimbeni, Nokusebenza Kwe-Baloxavir Marboxil Ezigulini Ezinempilo Enhle Eziyizingane Ezisukela Onyakeni Ongaphansi Ko-1 Ubudala Ezinezimpawu Ezinjengezemfuluwenza".

Ucwaningo lwaziwa ngokuthi i-'miniSTONE-1'.

- Inombolo yephrothokholi yalolu cwaningo ithi: CP40559
- Isihlonzi se-ClinicalTrials.gov salolu cwaningo sithi: NCT03653364
- Inombolo ye-EudraCT yalolu cwaningo ithi: 2018-002154-70