សេចក្តីស្្ើម

Dolutegravir (DTG) គឺជាឱេថប្រឆាំងសមសោគសេដេ៍ េ្ ថិតក ្ នុងបកនុម integrase inhibitors (INIs) ឬ integrase strand transfer inhibitors (INSTIs)។ Integrase inhibitors ស្វើការសោយោំងខ្ទ្រ់ integrase, ជាេង់េ៊តីមដដលសមសោគសេដេ៍បតរូវការចាំបាច់សដើម្តីអាចញាក់្រញ ្រូល viral DNA រ្រេ់វា ចូលសៅក ្ នុង DNA រ្រេ់សកាេថិកា CD4។ DTG គឺជាឱេថប្រឆាំងសមសោគសេដេ៍ ដដលមានភាពេន៊សបរោះជាងសគ ដតមានប្រេថិទ្ធភាពសៅក ្ នុងការ ្រង្ក្ រា្រសមសោគ HIV, អាចសប្រើម្ងក ្ នុង១ថថងៃ, សា ើយមថិនក្យមានភាពសាំសទ។ ឱេថសនោះេពវថថងៃមានការទទួលសាគា ល់ការសបចើនស�ើងថាជាជសបមើេជួរទតីមួយសដើម្តីពយាបាលHIV។

ការស្វើសតេ ្គ្តីនថិក (CLINICAL TRIALS)

សៅក ្ នុងការេថិកសាសប្រៀ្រស្ៀ្រជាមួយនឹងឱេថប្រឆាំងសមសោគសេដេ៍ស្សេងសទៀត DTG បតរូវបានសគរកសើញថាមានប្រេថិទ្ធភាពដូចឱេថស្សេងសទៀតសោោះដដរ សៅក ្ នុងចំសោមប្រជាជនដដលស្វើការេថិកសា (េូ មអានតាោងខាងសបកាម)។ ការេថិកសាំពតីការសប្រើ DTG ចំសោោះេ្នកជំងឺដដលធ្្ ្រ់បានទទួលការពយាបាលបានមានភាពសាំសទ integrase inhibitor បាន្រក្ហា ញថាេ្នកជំងឺចំនួន 69% មានកបមថិតវ ីរ៊៉េទា្រ្រំ្៊តដដលមថិនអាចរកសើញសទ (undetectable viral load) សៅអ៍ទតី២៤។

<table>
<thead>
<tr>
<th>Trial name</th>
<th>Drugs &amp; regimens compared</th>
<th>Patient population</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPRING-2</td>
<td>Dolutegravir vs. raltegravir</td>
<td>Treatment-naïve</td>
<td></td>
</tr>
<tr>
<td>SAILING</td>
<td>Dolutegravir vs. raltegravir</td>
<td>Treatment-naïve</td>
<td></td>
</tr>
<tr>
<td>FLAMIN-GO</td>
<td>Dolutegravir vs. darunavir</td>
<td>Treatment-naïve</td>
<td></td>
</tr>
<tr>
<td>SINGLE</td>
<td>Dolutegravir with abacavir and lamivudine vs. efavirenz with tenofovir and emtricitabine</td>
<td>Treatment-naïve</td>
<td></td>
</tr>
<tr>
<td>IMPAACT P1093</td>
<td>Dolutegravir with an optimized background regimen</td>
<td>Treatment-naïve</td>
<td></td>
</tr>
<tr>
<td>DAWN-ING</td>
<td>Dolutegravir with 2 nucleoside reverse transcriptase inhibitors (NRTIs) vs. lopinavir/ritonavir (LPV/RTV) with 2NRTIs</td>
<td>Treatment-naïve</td>
<td></td>
</tr>
</tbody>
</table>

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Tablet sizes of efavirenz 600 mg (top) and 200 mg (middle) compared to dolutegravir 50 mg (bottom).
Markings on the tablet, color, and design may differ among manufacturers.
ការបង្កើតយោបល់ (INDICATIONS)
DTG បានប្រើប្រាស់ជាមួយ abacavir (ABC) បានប្រើប្រាស់ lamivudine (3TC) ដែលអាចបង្កើតយោបល់លើជីវិតសាសន៍ (HIV-1 RNA <50 copies/mL) ប្រចាំ 48 ថ្ងៃ បន្ថែមគ្នាចំនួន 48 ថ្ងៃ ក្នុងការបង្កើតយោបល់ (ATV/r) និងមនេស្តរូបទឹកចន្លោះ fumarate/emtricitabine (TDF/FTC)។

សារបោះបង់ (SIDE EFFECTS)
តាមការកសិបយដែលបានបង្កើតយោបល់ DTG មានភាពច្រើនជាង efavirenz (EFV) ឬ or darunavir/ritonavir (DRV/r) ស្រើសទាោះរតីជាទូទៅអាចស្វាគមន៍ការបង្កើតយោបល់ដល់អត្ថបទិយវិធីជីវិតសាសន៍ដូចជាស្វាគមន៍មានការគុណការទឹកចន្លោះ។ ស្រើតាមការយល់បពមឱ្យ្សេពវ្សាយសលើទំងអាសន្ន វាលាក់កែងពីការបង្កើតយោបល់មានស្រូបសារជាមួយ neuropsychiatric នៅលើស៊ីនការបក្សិត្តន់ ័យពាក្យសោកបានោក់្រញ្ ហា។

ការយល់បពមឱ្យសប្រើ (DRUG-DRUG INTERACTIONS)
DTG បានប្រើប្រាស់ជាមួយ abacavir (ABC), lamivudine (3TC) និងមនេស្តរូបទឹកចន្លោះ fumarate/emtricitabine (TDF/FTC) ។
<table>
<thead>
<tr>
<th>Medicine</th>
<th>Interaction</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etravirine</td>
<td>CAS:89181-83-8, CAS:89181-84-9 DTG pronunciation</td>
<td>Dolutegravir interacts with etravirine, darunavir, atazanavir/ritonavir, lopinavir/ritonavir, darunavir/ritonavir.</td>
</tr>
<tr>
<td>Efavirenz</td>
<td>CAS:89181-83-8, CAS:89181-84-9 DTG pronunciation</td>
<td>Dolutegravir interacts with efavirenz.</td>
</tr>
<tr>
<td>Nevirapine</td>
<td>CAS:89181-83-8, CAS:89181-84-9 DTG pronunciation</td>
<td>Dolutegravir interacts with nevirapine.</td>
</tr>
<tr>
<td>Fosamprenavir</td>
<td>CAS:89181-83-8, CAS:89181-84-9 DTG pronunciation</td>
<td>Dolutegravir interacts with fosamprenavir.</td>
</tr>
<tr>
<td>Oxytetracycline</td>
<td>CAS:89181-83-8, CAS:89181-84-9 DTG pronunciation</td>
<td>Dolutegravir interacts with oxytetracycline.</td>
</tr>
<tr>
<td>Metformin</td>
<td>CAS:89181-83-8, CAS:89181-84-9 DTG pronunciation</td>
<td>Dolutegravir interacts with metformin.</td>
</tr>
<tr>
<td>Rifampin</td>
<td>CAS:89181-83-8, CAS:89181-84-9 DTG pronunciation</td>
<td>Dolutegravir interacts with rifampin.</td>
</tr>
</tbody>
</table>

**CONTRAINDICATIONS**

- **Etravirine:** Not recommended due to the risk of major drug interactions with Dolutegravir.
- **Efavirenz:** Not recommended due to the risk of major drug interactions with Dolutegravir.
- **Nevirapine:** Not recommended due to the risk of major drug interactions with Dolutegravir.
- **Fosamprenavir:** Not recommended due to the risk of major drug interactions with Dolutegravir.
- **Oxytetracycline:** Not recommended due to the risk of major drug interactions with Dolutegravir.
- **Metformin:** Not recommended due to the risk of major drug interactions with Dolutegravir.
- **Rifampin:** Not recommended due to the risk of major drug interactions with Dolutegravir.

**EVIDENCE GAPS**

- Evidence from clinical trials and observational studies is limited for Dolutegravir's efficacy and safety in the pediatric population.
- Further research is needed to better understand the long-term effects of Dolutegravir in children.
- Additional studies are required to evaluate the safety and efficacy of Dolutegravir in combination with other antiretrovirals in the pediatric population.

**A full list of countries where adult or pediatric generic DTG formulations can be marketed can be accessed from footnotes 18 and 19.**

**Malaysia, Sri Lanka, Thailand**
**Bangladesh, Bhutan, Cambodia, India, Indonesia, Laos, Myanmar, Nepal, Philippines, Vietnam**

**A full list of countries where adult or pediatric generic DTG formulations can be marketed can be accessed from footnotes 18 and 19.**

- **Rifampin:** Not recommended due to the risk of major drug interactions with Dolutegravir.
- **Dolutegravir:** Interacts with rifampin.

**AUTHOR’S NOTE:**

- The information provided is based on the current available data and may be subject to change.
- Patients and healthcare providers are encouraged to consult with a healthcare professional for personalized advice.
- For the latest updates and additional resources, please visit the relevant government and pharmaceutical websites.
REFERENCES


9. A voluntary license is an agreement that an originator company or a patent holder may make with other parties that provides the legal right to manufacture, import, and/or distribute the originator company’s pharmaceutical product.

10. Compulsory licensing is when a government allows a party other than the original patent holder to produce a previously patented product or process without the consent of the patent owner.


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