

MODERN ART FOR AFRICA

THE DOLPHIN-2 STUDY

Main results 2020

OCTOBER 2020



WHAT IS THE

DOLPHIN-2

STUDY?

DOLPHIN-2 is a clinical trial, in HIV positive starting ART in late pregnancy and comparing two first-line treatments:

- efavirenz/tenofovir disoproxil fumarate/emtricitabine
- dolutegravir/tenofovir disoproxil fumarate/emtricitabine.





WHO WERE THE WOMEN IN THE DOLPHIN-2 STUDY?

The trial participants were HIV positive women who had not started ART in Uganda and South Africa. They were aged at least 18 years and at least 28 weeks pregnant – so they started ART in the third trimester (last three months) of pregnancy.



HOW WERE THE TREATMENT GROUPS COMPARED?

The 268 women in the trial were randomised in a 1:1 ratio to the two antiretroviral treatment (ART) groups (dolutegravir- or efavirenz-based ART).

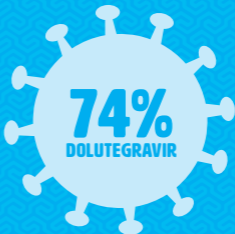
This means the participants were split randomly and equally among the two treatment groups.



The primary outcome (the most important outcome) was the proportion of participants with undetectable viral load less than 50 copies/mL at the first post-partum (after the baby is born) clinic visit – compared by group.

The primary safety outcome was side effects in the mothers and babies before the first post-partum visit – also compared by group.

**VIRAL
LOAD <50**



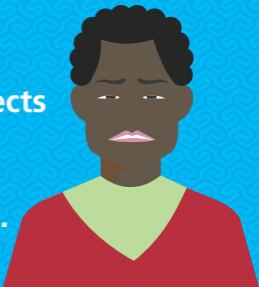
WHAT WERE THE MAIN RESULTS?

At the first post-partum visit 74% of mothers in the dolutegravir group had viral loads less than 50 copies/mL compared with 43% in the efavirenz group.

SERIOUS SIDE EFFECTS



And 22% of mothers in the dolutegravir group reported serious side effects compared with 11% in the efavirenz group.




WERE THERE

ANY OTHER

DIFFERENCES?


There were no differences in premature births (before 37 weeks) or very premature births (before 34 weeks) between the two births.





Three babies in the dolutegravir group were infected with HIV but this was most likely because they were infected in the womb before the mothers started ART.

There were also four stillbirths in the study (three in the dolutegravir and one in the efavirenz group). None of these were judged to be related to the HIV treatment.



WHAT ELSE CAN WE LEARN FROM THIS STUDY?

It is very important to note that women starting ART late in pregnancy are a vulnerable group. They are more likely to have poor outcomes than those already on treatment or starting earlier in pregnancy.

WHAT MESSAGES CAN WE SHARE WITH THE COMMUNITY?

Everyone with HIV
needs to take ART
as soon as possible
– this includes
pregnant women and
women who plan
to get pregnant.



Pregnant women (and everyone) who do not know their status should get tested for HIV and take treatment as early as possible.

The DolPHIN-2 results, alongside evidence from other trials and HIV treatment programmes, support the World Health Organization (WHO) and national guidelines recommending transition to dolutegravir-based first-line ART for everyone with HIV, including pregnant women.



WHAT WILL HAPPEN NEXT?

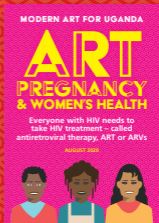
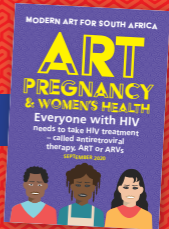


The study is ongoing and will follow the mothers and babies to 72 weeks post-partum, and will continue to compare the two treatment groups.

WHERE CAN I LEARN MORE ABOUT ART & PREGNANCY?

We have also produced a booklet that explains more about HIV and pregnancy and using dolutegravir- and efavirenz-based ART.

We have versions for South Africa and Uganda.





LEARN MORE

ABOUT DOLPHIN-2

Dolphin-2 is a multinational project, led by the University of Liverpool and funded by Unitaid.

These results were published in an important medical journal called *The Lancet*, May 2020:
[www.thelancet.com/journals/lanhiv/article/PIIS2352-3018\(20\)30050-3/fulltext](http://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(20)30050-3/fulltext)

Learn more about DolPHIN-2 at:
dolphin2.org



Find out more about treatment
and the free app at:
www.modernartforsouthafrica.co.za



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