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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

November 2023 Table of Contents

Database Lock Is Complete!

On Monday, November 13th, the REPRIEVE clinical database was locked! THANK YOU to every site team for your incredible efforts to complete study termination visits, enter data, respond to queries, and sign-off eCRFs. We achieved these significant milestones through *communication, collaboration, and community*.

*Upcoming Study Closure Deadlines**

- November 20th, 2023: Unblinding notification will be emailed to Site PIs and Study Coordinators.
- November 27th, 2023: Clinical research sites must report study closure to your local IRB/EC**
- On or around January 1st, 2024: Clinical research sites must deregister the REPRIEVE protocol with DAIDS protocol registration after confirmation of study closure with IRB/EC. Please see pg. 58 of the DAIDS Protocol Registration Manual.

*Please know that sites may continue to download participant casebooks after the deadline for eCRF sign-off.
**For sites utilizing the CCC's Advarra, the CCC will report study closure on your behalf.

Unblinding Notification

The unblinding notification will be sent to sites on November 20th, 2023. The Site PI and CRS Coordinator will receive an email from the REPRIEVE Data Managers with the information needed for unblinding. If you would have any questions about this, please contact Ken Wood (wood@frontierscience.org).

Translations of *Template Unblinding for Participants Letter* are Now Available

The template unblinding letter for participants has been translated to Spanish, Portuguese, and French (Canada) with more languages to come! Use the links below to download these translations. To request translation to another language, please email Marissa Diggs (mdiggs@mgh.harvard.edu).

Spanish Unblinding Letter
Portuguese Unblinding Letter
French (Canada) Unblinding Letter

Stay in Touch: REPRIEVE Newsletter Coming Soon!

Although the REPRIEVE Trial is closing, data analysis is far from complete! In the near future, we plan to share results from the Mechanistic Substudy (A5333s) and more!

To keep up with the latest REPRIEVE news and additional study findings, sign up for the newsletter using the link below:

REPRIEVE Trial Newsletter Sign Up Form

Please share this with anyone who participated in REPRIEVE at your site and anyone who might be interested in receiving information about REPRIEVE.

REPRIEVE Results Graphical Abstract

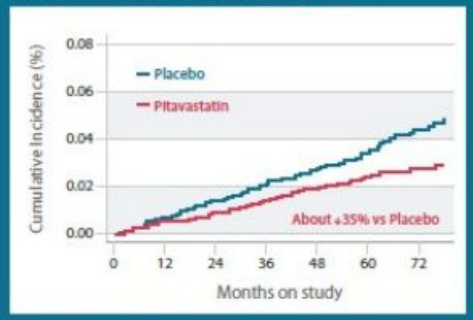
How can people living with HIV (PWH) protect their heart health?

People living with HIV (PWH) are at risk of developing cardiovascular disease.

The Randomized Trial to Prevent Vascular Events (REPRIEVE) enrolled **7,769** PWH around the world to test whether pitavastatin (vs. placebo) can prevent cardiovascular disease in this population.

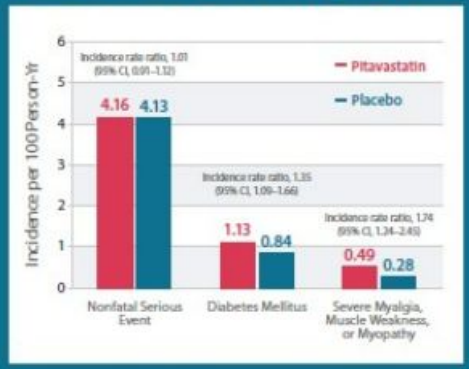
Each heart on the map represents a REPRIEVE clinical research site.

Time to major adverse cardiovascular event (like first heart attack or stroke)



Pitavastatin reduced the incidence of the primary endpoint, major adverse cardiovascular events (MACE), by 35% compared to placebo over an average of approximately 5 years of follow up.

Adverse events diagnosed during study period



Adverse events were similar between participants taking pitavastatin vs. placebo.

- Diabetes rates increased in the pitavastatin group, however pitavastatin reduced major adverse cardiovascular events even among PWH with diabetes.
- Muscle-related symptoms were higher in the pitavastatin group but were mostly mild and only 1% withdrew for muscle-related symptoms.

Conclusion

In PWH at low-to-moderate traditional risk for cardiovascular disease, pitavastatin is safe, effective and prevents major adverse cardiovascular disease events like heart attack and stroke.

DEFINITION OF TERMS:

Cumulative incidence is the proportion of people who experience an event during the study period. This can be thought of as the risk of experiencing a major adverse cardiovascular event in this study.

Incidence per 100 person-years is the rate that people experience an event during the study period. Person-years is a measure of how much time the people have spent in the study.

A **95% confidence interval** (95% CI) is the range of values that we expect a data estimate to fall between 95% of the time if the study was repeated.

For more information, please visit the REPRIEVE Trial website: www.reprievetrial.org

Now available! The REPRIEVE Team has developed a graphical abstract of the REPRIEVE primary results published in The New England Journal of Medicine. This graphical abstract is available to download here and on our new webpage. We hope this will be a helpful resource to spread the word about REPRIEVE's results!

Webpage to Support REPRIEVE Results Sharing

The REPRIEVE CCC has launched a central webpage where various REPRIEVE results materials are posted.

The materials include:

- Graphical abstract of trial results
- Statin guidance for participants and providers
- Slide templates for presentations to providers
- Slide templates for presentations to the community
- Participant FAQs, and more!

Visit this new page on the REPRIEVE website and share this with your community. Go to: https://www.reprievetrial.org/learnmore/results-of-the-reprieve-trial/.

Change of Date: Next Team/Site Call! Tuesday November 28th

Tuesday November 28th is the final planned team/site call for REPRIEVE. This is a momentous occasion during which we will share the final results from the Mechanistic Substudy that were presented on Sunday, November 12th at the American Heart Association Conference. We'll also take a time to recognize site teams for their incredible contribution to REPRIEVE. Please make every effort to join this call. If you haven't received the invite please email Marissa Diggs, mdiggs@mgh.harvard.edu.

If you have any questions in advance of the site call we'd love to hear from you! Please email them to Katie Fitch at the REPRIEVE CCC.

1:00 PM PERU (PET)
1:00 PM US (EST)
1:00 PM HAITI (EST)
2:00 PM PUERTO RICO (AST)
3:00 PM BRAZIL (BRT)
8:00 PM BOTSWANA (CAT)***
8:00 PM SOUTH AFRICA (SAST)***
8:00 PM ZIMBABWE (CAT)***
9:00 PM UGANDA (EAT)***
11:30 PM INDIA (IST)***
1:00 AM (November 29th 2023) THAILAND (ICT)***
****We do not expect site staff to join these calls during their off-work hours*. Instead, we will post slides from this call on the A5332 PSWP.

Remember that questions are always welcome at actg.corea5332@fstrf.org

For future reference, all newsletters are available on the REPRIEVE Website

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