Part of EU-RESPONSE

EU SOLIDACT

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NEWSLETTER #5

Bari-SolidAct has stopped inclusions for immunocompetent patients.

Inclusion of immunocompetent participants will stop after Monday 7th March 2022 but immunocompromised patients should still be included.

On March 3rd, the Recovery trial reported results from their baricitinib arm, finding a significant absolute risk reduction in 28-day mortality from 14% to 12% compared to standard of care, as well as publishing a meta-analysis showing that baricitinib reduces the relative mortality rate by around one fifth.

Based on these results and discussions with the DSMB, the Trial Steering Committee has decided to stop inclusions to Bari-SolidAct in immunocompetent participants. However, as the safety and benefit of immunomodulators is still not determined in immunocompromised patients, Bari-SolidAct will continue to include immunocompromised participants.

An amended protocol restricting inclusions to immunocompromised participants has been prepared. Due to a new regulatory system in Europe (CTR), there might be some delay in the regulatory approval of this amendment.

It is important that all site staff are informed about these changes so that only immunocompromised participants are included. Please ensure that you inform all staff at your site about the changes.

It is important that the eCRF is completed for all included participants up to now so that the database can be prepared for analysis and publication.

QUESTION & ANSWERS? SEE OUR INTERNET PAGE EU-SOLIDACT - EU-RESPONSE