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Subject: RE: tardis

Date: 18 March 2016 at 16:40

To: Philip Bath (philip.bath@nottingham.ac.uk) philip.bath@nottingham.ac.uk, Helen Rodgers helen.rodgers@newcastle.ac.uk

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Dear Philip and Helen

The IDMC for the TARDIS trial met on Wednesday and again this afternoon.

Our unanimous recommendation to the steering committee and sponsor is that the trial should stop because of a more than doubling of the risk of bleeding in all categories of bleeding, with a clearly statistically significant increase in the risk of the composite of major and fatal bleeds, with no compensatory evidence of benefit for the primary outcome.

We recommend that you stop randomisation into the trial as soon as you possibly can and make every effort to stop the use of triple therapy in those already randomized.

We encourage you to complete follow-up for those already randomised and to plan for the finalisation of the study database with subsequent analysis and publication of the results.

Ian Ford

On behalf of the TARDIS IDMC

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