

NEWS

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We have waited with sending the first PRECIOUS newsletter until there was **very good news**, and this has now come: PRECIOUS has been approved in the Netherlands and via the VHP in five other countries! The trial eCRF is almost final. This means that patient recruitment can start shortly!

Ethical Approval (IRB/VHP)

In the past few weeks, PRECIOUS has been approved via the Voluntary Harmonisation Procedure (VHP) for Estonia, Hungary, Germany, Italy, and the UK, and by the central Review Board for the Netherlands!

This is a major step forward and means that the start of patient recruitment is coming very close. The first patient will hopefully be included at the UMC Utrecht by the end of March, which will be two months ahead of schedule. The approval by the IRB and VHP also means that the process of requesting approval in the other participating countries can be started. The trial has already been submitted to the Competent Authorities of the countries which participated in the VHP, and will be submitted to those of Greece, Norway and Poland shortly, followed by the national ethics committees in all countries. We thank all who have contributed very much for their efforts!

Involvement of Antibiotics in PRECIOUS

The results of the PASS and STROKE-INF trial do not support a benefit of prophylactic antibiotics in patients with acute stroke. However, several important limitations of these two trials could explain the observed lack of benefit. First, PASS included patients with on average mild strokes (median NIHSS, 5) and consequently had a low number of patients with post-stroke infections in the control group. Secondly, in STROKE-INF, antibiotics were started late (within 48 hours), and a substantial number of patients in the control group (34%) also received antibiotics. In addition, a wide range of different antibiotics was used. The use of a cluster-randomised design and low recruitment rates leads to a substantial risk of bias in STROKE-INF.

We therefore think prophylactic antibiotics still hold promise. Importantly, PASS showed that the use of preventive ceftriaxone was safe. Testing ceftriaxone in PRECIOUS is therefore still warranted!

Project Website

The website of the PRECIOUS project is now online. Please visit www.precious-trial.eu to read general information about the project (including details on the different work packages) as well as descriptions of all partners who are involved in PRECIOUS.



The website contains sections for scientists, lay people and patients, and you will find project news there, too. If you would like to subscribe to our quarterly newsletter, please visit the PRECIOUS homepage and insert your e-mail address at the bottom of the page.

You are also kindly invited to follow us on Twitter under the following handle: @precious_trial

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