NTNU – Trondheim
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TRONDHEIM UNIVERSITY HOSPITAL

NORWEGIAN CANCER SOCIETY

ACHILES newsletter

September 2020

Changes to the WebCRF and schedule for thoracic radiotherapy:

Since there are strong indications of a survival benefit of 60 Gy compared with 45 Gy, we will stratify for TRT-schedule when patients are randomized. For technical reasons, we cannot make changes to the current CRF ("ACHILES Main study period"). We will therefore make a new version, which will be active from September 14.
This means that all patients who are randomized after September 14th should be entered in the new CRF ("ACHILES Main Study from Sept 14 2020"), regardless of which TRT schedule you use. Patients who are already randomized should not be moved to this new CRF. We will rename the current CRF from "ACHILES Main Study Period" to "ACHILES Main Study until Sept 13th 2020", and you should continue entering data in this CRF. The only change to this CRF will be that the randomization module will be deactivated.

As mentioned in our summary of the discussion about TRT-schedule earlier this summer, all sites are free to decide which schedule to use. And we understand that this is difficult to have a strong opinioin about before the results of our previous trial have been published. We have submitted the manuscript and hope that it will be accepted in the near future.

Thus, it is difficult to know how many sites that will actually change schedule, and consequently, it is not possible to know if this will have any impact on the statistical assumptions for our trial. The plan is to ask all the sites later this autumn. We will closely monitor the use of the two TRT-schedules, and adjust the total sample size if needed.

Friendly reminder!

We would appreciate if you enter data in the WebCRF as soon as possible after each study event and no later than a week after each visit. For patients who are included after chemoradiotherapy, please complete the ACHILES Induction Period as soon as possible after inclusion. Unfortunately we see that in some cases data are entered too late, which makes data-monitoring difficult.

Protocol version 1.3:
A new version of the protocol, version 1.3, has been sent to all National Coordinating Investigators, and we expect it to be approved by all countries this autumn. It has already been approved by the Ethics committee in Norway, and we expect to have approval from the Medicines Agency within a few weeks.

The most important change is that we now allow for thoracic radiotherapy of 60Gy, and that we also allow using G-CSF according to local routines. There are also some other additions, but those are mainly clarifications of study procedures in response to questions and comments we have received since the last amendment.

Data collection manual version 5:
Please find attached a new version of the data collection manual. The changes include updated guidelines for the WebCRF (pages 3 and 7) and information about destruction of expired study drug on page 12.

Invoicing:
Invoices regarding site grants should always be sent to achiles@stolav.no for registration.

Site status:
Please notify us of any changes in study personell at your site.

Contact information:
E-mail trial office: achiles@stolav.no
E-mail PI: bjorn.h.gronberg@ntnu.no
https://www.ntnu.edu/ikom/achiles-trial
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Inclusion status:
Below are updates on inclusion and randomization in the trial. A total of 105 patients are currently included. Antonius Ziekenhuis, Utrecht and Erasmus MC, Rotterdam have just included their first patients, which means that the Netherlands now are fully on board. Congratulations!

The inclusion rate is steadily gathering speed: 35 patients have been included since March.