NTNU – Trondheim
Norwegian University of
Science and Technology

ST. OLAVS HOSPITAL
TRONDHEIM UNIVERSITY HOSPITAL

NORWEGIAN CANCER SOCIETY

ACHILES newsletter

March 2020

COVID-19:
Here in Norway, the activity at our hospital is quite changed due to the ongoing pandemia, which has consequences for our clinical research. This is probably the situation also for most of you.

The standard chemoradiotherapy for LS SCLC patients will presumably be delivered as close to standard routines as possible, but it may not be possible to conduct the other parts of the ACHILES trial as planned.

It would, however, be good if we do not loose too much information, and it may also be that patients wish to continue on atezolizumab - either now or when the situation hopefully returns to normal. *In this very special situation, we will allow more protocol adaptations and deviations*, and you are encouraged to contact us to discuss how to best care for our patients and still collect the essential study information if you are not able to fully comply with the study protocol.

In case of any COVID-19 infections in study participants, please find attached a guideline for reporting such infections.

Roche confirms they do not expect any problems with supplying atezolizumab for the trial.

Data entries:
We would appreciate if you enter data in the Web-CRF as soon as possible after each study event, and at least in a normal situation, no later than a week after each visit.

We continuously control the data entered in the Web-CRF, and it is difficult to keep an overview of these data-checks if data entry is delayed.

Furthermore, most queries arising from this central data control are generated and sent to sites in the Web-CRF, though some queries will also be sent by e-mail from the ACHILES trial office.

Investigators Brochure:
Please find attached an updated amendment to the Investigators Brochure. The changes consist of updated guidelines for management of side-effects of atezolizumab.This should also be uploaded to your ISF.

Patients exiting the trial:
We have experienced that some sites have interpreted the criteria for discontinuation of study treatment differently, and will appreciate if you contact PI if you consider to discontinue patients for other reasons than disease progression.

Inclusion status:
Below are updates on inclusion and randomization in the trial. A total of 70 patients are currently included.

Kantonsspital Winterthur have just included their first patient, which is the first patient in Switzerland. Congratulations!

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

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