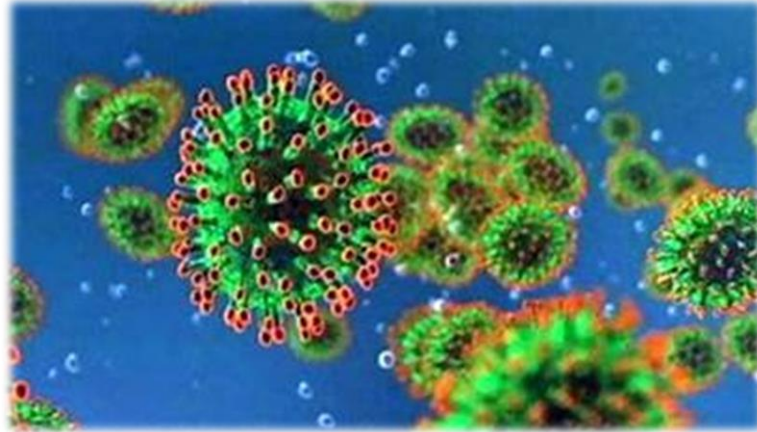




March 2020

EXTRA NEWSLETTER SSG XXII

Dear investigators and research coordinators/nurses in SSG XXII,



Corona virus and Covid-19 infection

In all participating countries we now experience an international health emergency. This may of course also influence the situation regarding the patients in the SSG XXII trial, their visits, blood sampling and investigations, and research staff may also be concerned. The security for our patients is of the highest priority for the SSG, and we will hereby give some guidance regarding reasonable protocol violations during the present crisis. Some sites and national coordinators have already been in touch with the SSG with questions.

There may be national and/or local regulations or recommendations regarding hospital visits etc. which must or may be followed. There may also be individual patients who are afraid to visit the hospital, an environment with a potentially high contagious risk. Therefore, the SSG will give the following guidelines/recommendations:

1. The most important action in the follow-up of the patients in the trial, both those on imatinib and those in follow-up without study medication is the abdominal/pelvic CT scan. If the patient does not have any present symptoms typical of Covid-19 (coughing, fever etc.), the CT scan must be done, following the hygienic precautions in use at the department. If Covid-19 is verified or suspected, the CT scan may be postponed as long as necessary.
2. Note that any Covid-19 infection must be reported as an adverse event, and as a SAE if hospitalization took place.

3. Scheduled visits are recommended if they are not considered to pose any hazard for the patient, including the contagious risk of travelling in public transports. In such cases, and also if the patient is afraid or does not agree to come to the study site because of the corona virus, the visit may be substituted by a thorough telephone call to inquire about side effects, symptoms, QoL etc. Naturally, you will then refrain from a physical examination.
4. Standard laboratory tests may be taken close to home, whereas no research samples may be taken at that visit.
5. Hopefully, not more than one visit is substituted by a telephone contact, and you must return to the protocol visit schedule as soon as the regulations and recommendations from the authorities have been withdrawn.
6. Every deviation from the protocol must be registered on a written note-to-file or form, which must be filed at the site with a copy to the SSG secretariat.
7. It is of utmost importance for the SSG XXII trial that no potential new patients are missed because of the pandemia! Remember that you have a three months window during which you may randomize the patient – from at least 35 months on adjuvant imatinib to not more than 38 months. Therefore, try to recruit the patient early within the window, and, if impossible, that time you may have three more months to hope for an improvement of the situation.

Further or modified guidelines may follow, and the SSG welcome you to contact us with any questions regarding the trial in relation to the corona virus situation.

For the SSG secretariat

Mikael Eriksson

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