EU SOLIDACT

Part of EU-RESPONSE

Bari-SolidAct Trial Newsletter

GRAND OPENING!

EU SolidAct opened the first centre on May 28th, and since then, 9 sites have opened in Norway and the first site has opened in France. Although the pandemic is rapidly declining all over Europe, our initial experience has been that both patients and investigators have been enthusiastic about participating in this trial. With your help, we aim to include as many patients as possible, and prepare for the fourth wave.

We will keep you updated with regular newsletters that will also be available on our webpage, which we will announce soon, together with protocols, presentations from kickoff meetings, tutorials including video links for eCRF training, information about safety reporting, teaching material for site staff, and frequently asked questions.

In this first newsletter we will answer some of the questions we have received regarding the protocol that have come up while initiating the trial. Some of these answers will require minor protocol adjustments or that will be amended in the next version of the protocol.

Please send us questions or comments when you open new sites so that we can respond to your comments and share experiences with other sites.

On behalf of the sponsor team, I wish you all a good summer!

Oslo, 11th June 2021
Marius Trøseid, Chief Investigator

Q & A

Do you have a question or comment that we could feature in our next newsletter?

Contact us on solidact@ous-hf.no

Q: Why do I have to register drugs at screening, and which drugs should be registered?

A: We want to capture regular drugs taken the last 14 days before admission, as well as drugs as part of Standard of Care for COVID treatment after admission, but before screening. These data will be used to describe the patient population at baseline, and also for planned subgroup analyses of patients receiving different forms of SoC, such as remdesivir and dexamethasone.

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Q&A

Q: Safety lab : certain markers such as procalcitonin are not routinely available or very expensive to measure at my hospital. Will it be considered a protocol deviation if this is not measured?

A: Although frequent collection of inflammatory markers (LDH, ferritin, D-dimer, CRP, procalcitonin) goes beyond the need for safety assessment, these analyses are considered important as end point variables for assessing a potential anti-inflammatory effect of tested drugs without the need of biobanking.

* If it is not possible to analyse these parameters routinely, the following time points should be prioritized:
  * Baseline
  * Day 8 (±1 day)
  * Day15 (±1 day)
* If certain markers (i.e. procalcitonin) are not available at a site, and therefore not analysed, this will not be considered a protocol deviation.

Q: Concomitant medication : is it necessary to collect all drugs if the list of medication is very long?

A: All concomitant medication should be registered. However, if it is not feasible to register all concomitant medication for a patient, the following drug classes should be prioritised:

- Conditions treated with drugs that could trigger adverse events of special interests (AESI). This category includes severe infection (treated with antibiotics, antivirals), reactivation of infections (treated with immunomodulators), thromboembolism (treated with anticoagulants), hepatotoxicity (check concomitant medication carefully, including but not limited to antibiotics, antipsychotics, antiepileptics, statins, paracetamol), gastrointestinal bleeding/perforation (antacids, platelet inhibitors, NSAIDs)
- Changes in medications used to treat chronic comorbidities such as ACE-inhibitors, AT2 inhibitors, statins.
- Drugs as part of Standard of Care (SoC), in particular tocilizumab and changes in prescribed steroid dose

The following medications are frequently changed and dose changes are therefore less important to register:

- Intravenous fluid therapy
- Sedatives
- Anaesthetics
- Vasopressors
- Antitussives
- Insulin

Q: Time Windows : Can you clarify the time windows for assessment in the Schedule of Assessments (SoA) table in the protocol? What does Day 3, 5, 8 (±1 day) mean?

A: The assessments should be performed on: Day 3 (±1 day), Day 5 (±1 day), Day 8 (±1 day). Baseline is Day 1 (the first day of intervention).

Have news you'd like to share?
Send it to us on solidact@ous-hf.no

DRUG ORDERS

Drug orders sent by Inserm must arrive at Theradis Pharma by 4 pm which means that Inserm needs to be notified way before that. As soon as the drugs arrive at the site, an acknowledgement of receipt and temperature readings must be sent to solidact@theradispharma.com immediately and not later than 24 hours after receipt of drugs.