



STopping Aminosalicylate Therapy in Inactive Crohn's Disease (STATIC) Study: A Randomized, Open-label, non-inferiority Trial

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STATIC Website Portal: www.static-trial.com

The STATIC website and investigator portal is key for useful site documents, as well as current and past Newsletters.

Thank you everyone for your continued efforts to recruit for STATIC!

Number of sites activated:

➤ 13

Number of patients randomized:

➤ 15

Urine collection containers, labels and storage boxes are coming.

LAB COLLECTION:

- *If a patient has recent lab work, repeat testing for STATIC is not always necessary. Please refer to the protocol for acceptable time frames.*
- *Blood Urea Nitrogen has not been collected with regularity. Please be vigilant when completing lab requisitions to include BUN and all other testing*

Check boxes imbedded in the text of the ICF continue to be problematic, please be diligent in bringing this to your participant's attention.

As per the protocol, a physical exam is necessary for enrollment in STATIC. Additionally, HBI must be performed by a physician. Please ensure that all team members are aware.

Don't forget about patient diaries to be issued at Visit 2

RANDOMIZATION:

*When a participant is randomized to the withdrawal arm, they **must immediately stop taking their 5ASA.***

Only the collection of urine for freezing is necessary while the patient is on their 5ASA.

All other labs should be done ASAP, but it is imperative that drug withdrawal aligns with the date of randomization.

CASE REPORT FORM ENTRY:

- *Empty fields cause queries – please fill out the CRF within 5 days of patient a visit*
- ***If you are having FCP analyzed centrally** – Enter “NO” for “local lab sample collected?” And provide a reason in the text field (i.e. freezing sample for batch shipment)*
- *Please indicate how urinalysis has been performed; via dip stick or lab requisition – either method is acceptable*
- *Non-CD related surgical history collection (at the screening visit) is only for the previous 12 months*

Visit 3 (6 month follow up visits), have started to occur. If your site needs help in tracking follow up visits, let us know. Kathleen has a great tool to aide in scheduling follow ups.