# Implementation of a serum monitoring protocol for Infliximab in patients with Inflammatory Bowel Disease

Mafalda Cavalheiro; Maria José Rei; Ana Rita Silva; Patrícia Batalha Silva; Carolina Marques; Miriam Capoulas

- Hospital da Luz Lisboa (Portugal)

Keywords: Clinical pharmacy, Clinical pharmacy services, Dose optimization, Drug prescribing and dosing, Pharmacokinetics og -dynamics, Therapeutic drug monitoring

# Why was it done?



Low serum Infliximab levels are associated with:

- Loss of response;
- Development of immunogenicity.



Therapeutic levels without control of inflammatory activity may inform about the need of changing the therapeutic class.

While monitoring serum levels in the absence of response is already well established, the proactive monitoring of serum levels at defined timings during the induction and maintenance phases of therapy is beginning to be recommended by several leading organizations.

## What was done?



Establishing a protocol for proactive serum monitoring of Infliximab in inflammatory bowel disease, to guide the interpretation of serum levels, optimize dosage and therapeutic response.

#### How was it done?

Implementation took place in several stages:



- Theoretical and practical training;
- Discussion and drafting of a technical guideline including a monitoring protocol with the Gastroenterology team.



- Organization of the sample collection and analysis circuit. Colletion at w6 and/or w14 and according to therapeutic plan - proactive strategy. In case of lack of response - reactive strategy.
- Analytical technique → rapid test that allows the detection of Infliximab levels and anti-Infliximab antibodies.



Dose adjustments were carried out with the support of population pharmacokinetic models (DoseMeRx software), interpreted in the context of the overall response assessment in conjunction with the clinical team.

#### What next?



The strategy of proactive monitoring and dose intensification may have contributed to achieving and maintaining the response to treatment with Infliximab, but the small number of patients and the duration of the analysis call for further analysis.

### What has been achieved?





n=15 Ulcerative Colitis: 11 (AGE) 33 years Crohn's Disease: 4





24 tests Proactive strategy: 21 Reactive strategy: 3



60% below the reference range considered

64% of the patients had a dose intensification

76% of the patients obtained and maintained response



Follow-up was less than one year in most cases.

#### Serum Concentration at Week 6









