Inclusion Criteria

1. Male or female patients, 18 years or older

2. Patients with IBD who are registered in the GEDII registry, including:
   - ❖ Patients with moderate to severe, active Crohn's disease who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies
   - ❖ Patients with fistulising active Crohn's disease who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy)
   - ❖ Patients with moderate to severe active ulcerative colitis who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

3. Patients who initiated Inflectra according to physician's criteria, including:
   - ❖ Anti-TNF-alfa-naïve patients
   - ❖ Patients on treatment with Remicade with stable clinical response (defined as Harvey-Bradshaw Index <5 – for CD patients; or Mayo score < 2 – for UC patients) and who switched to Inflectra

4. Inflectra managed according to local SMPc

5. Patients who gave their consent to be included in the GEDII Registry

Exclusion criteria

1. Patients who are not eligible for anti-TNF-alfa therapy

2. Patients who are being treated with any investigational agent

3. Patients who are not willing to comply with routine clinical appointments

Laboratory Testing

Serum Samples:

- ➢ For all time point, marked in the chronogram, collect 5 mL of blood to a serum gel tube
- ➢ Blood must be left for 1 hour at room temperature to assure coagulation
- ➢ Centrifuge at 3000 rpm, for 10 min
- ➢ Collect serum to two cryovials
- ➢ Identify cryovials with the label provided in the kit
- ➢ Freeze and store serum samples at -20 ºC until refrigerated transport is provided

Fecal Samples:

- ➢ Each sample should be collected with the EASYSample collection Kit
- ➢ The tube must be identified with the label provided in the kit
- ➢ Send samples to the central laboratory within 48 hours
- ➢ **Contact GEDII for transport**

Study Duration

The overall duration of the study is three years (1 year of recruitment + 2-year observation period).

Study Timelines

The study is expected to start during 2015. Study closure is expected to occur 2nd Quarter of 2018.

For any study related questions, please contact:

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SIMREGISTER

Title: A study in the real-world practice to evaluate the impact of bio**sim**ilar infliximab (Inflectra) in clinical outcomes in patients with inflammatory bowel diseases: a 2-year longitudinal analysis from the GEDII **Reg**istry

Study sponsor: Grupo de Estudo da Doença Inflamatória Intestinal (GEDII)

Name of Scientific Coordinator: Prof. Fernando Magro

Primary Objectives

- To evaluate the impact of Inflectra in inducing clinical response among biologic-naïve patients with IBDs registered in the GEDII Registry followed for two years.
- To evaluate the impact of Inflectra in inducing clinical remission among biologic-naïve patients with IBDs registered in the GEDII Registry followed for two years.
- To evaluate the impact of Inflectra in promoting mucosal healing, among biologic-naïve patients registered in the GEDII Registry followed for two years.
- To evaluate the impact of Inflectra in promoting biomarkers remission by normalization of calprotectin.

CHRONOGRAM A (applicable for CD or fistulising CD patients)

	Infliximab															
	Induction period*			Maintenance period – data collection time point (24 month follow up)												
Information to be collected	Day1 or basal	W 2	W 6	W 14	W 22	W 30	W 38	W 46	W 54	W 62	W 70	W 78	W 86	W 94	W 102	Or completion of Fup[3]
Date of Birth	X[4]															
Sex	X[4]															
Height	X[4]															
Weight	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
BMI	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Smoking status	X[4]															
Medical history	X[4]															
Comorbidities	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Disease presentation	X[4]															
Diagnosis CD, location, steroid, behaviour, prognostic classification.	X[4]															
Clinical activity HBI)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Nr of draining fistulaes (fistulising CD)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
PDAI (perianal CD)	X	X	X	X	X		X		X		X		X		X	X
Dose of Inflectra administered	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Endoscopy	X								X						X	X
Concomitant therapies	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Routine laboratory parameters	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Serum infliximab levels[1]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Anti-drug antibodies[1]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Fecal sample (calprotectin levels)[2]	X	X	X	X	X		X		X		X		X		X	X
Adverse reactions	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Use of health resources	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

*Data related with induction period **will only be collected** for biologic-naïve patients stating Inflectra.
Data related with maintenance period is applicable both for biologic-naïve patients and patients who switched from Remicade.
W = week, HBI = Harvey Bradshaw Index, PDAI, Perianal Disease Activity Index.
[1]Blood sample to be collected prior to each infusion of Inflectra at the scheduled appointment. Sample will be analysed by Central Laboratory.
[2]Stool sample to be collected and sent for Centro Laboratory
[3]Patients in maintenance with Inflectra at study inclusion will be followed every 8 weeks (or every 6 weeks, if required) until completing the 24-month follow up period;
[4]Basal data to be collected, regardless of the patient's treatment status at study inclusion

CHRONOGRAM B (applicable for UC patients)

	Infliximab															
	Induction period*			Maintenance period – data collection time point (24 month follow up)												
Information to be collected	Day1 or basal	W 2	W 6	W 14	W 22	W 30	W 38	W 46	W 54	W 62	W 70	W 78	W 86	W 94	W 102	Or completion of Fup[3]
Date of Birth	X[4]															
Sex	X[4]															
Height	X[4]															
Weight	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
BMI	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Smoking status	X[4]															
Medical history	X[4]															
Comorbidities	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Disease presentation	X[4]															
Diagnosis CD, location, steroid, behaviour, prognostic classif.	X[4]															
Clinical activity (Partial Mayo)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Dose of Infllectra administered	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Endoscopy	X			X					X						X	X
Concomitant therapies	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Routine laboratory parameters	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Serum infliximab levels[1]	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X
Anti-drug antibodies[1]	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X
Fecal sample (calprotectin levels)[2]	X	X	X	X	X		X		X		X		X	X	X	X
Adverse reactions	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Use of health resources	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

* Data related with induction period will **only be collected** for biologic-naïve patients starting Inflectra. Data related with maintenance period is applicable both to biologic-naïve patients and patients who switched from Remicade.
[1] Blood sample to be collected prior to each infusion of Inflectra at the scheduled appointment. Sample will be analyzed by Central Laboratory.
[2] Stool sample to be collected and sent for Central Laboratory
[3] Patients in maintenance with Inflectra at study inclusion will be followed every 8 weeks (or every 6 weeks, if required) until completing the 24-month follow up period;
[4] Basal data to be collected, regardless of the patient's treatment status at study inclusion. W = week