

“Azathioprine maintenance therapy in steroid-refractory Ulcerative Colitis responsive to i.v. Cyclosporine A: Is a ‘therapeutic bridge’ with oral Cyclosporine A necessary?”

Aim: to compare the effectiveness and safety of two different strategies (with and without oral CsA as therapeutic bridge to AZA) for maintenance therapy in patients with steroid-refractory UC, responsive to i.v. CsA.

Inclusion criteria

- Suffering from a moderate or severe acute attack of UC – as defined as a modified Truelove-Witts score >10 (see ANNEX) – not responding to 3 days of i.v. steroid therapy (60 mg/day methylprednisolone)
- Response to 7 days i.v. CsA (4 mg/Kg/day), as assessed by an “inactive” modified Truelove-Witts index (see ANNEX)
- Absence of colonic CMV infection as assessed by immunohistochemistry, prior to CsA therapy
- Informed consent

Exclusion criteria

- Disease involving less than 50 cm of distal colon
- Arterial hypertension
- Increased serum creatinine
- Blood granulocyte count lower than 1,500 cells/mm³
- Toxic megacolon
- Active infection
- Severe associated disease

Routine Lab.	x	x ¹	x	x	x	x	x	x	x	x	x	x	x	x
CRP	x		x	x	x	x	x	x	x	x	x	x	x	x
Truelove-Witts	x		x	x	x	x	x	x	x	x	x	x	x	x
Serum CsA levels	x		x ²	x ²	x ²	x ²								
AE recording		x	x	x	x	x	x	x	x	x	x	x	x	x
QoL (IBDQ)	x					x				x				x
Compliance			x	x	x	x	x	x	x	x	x	x	x	x
Colonoscopy-biopsy								x						x

¹Only blood cell counts

²Only in the BRIDGE group