

Ciclosporin and azathioprine treatment in severe ulcerative colitis: a double-blind controlled trial to evaluate short and long-term outcome

Submission date 26/05/2005	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
Registration date 20/07/2005	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 30/07/2014	Condition category Digestive System	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Acronym

UC CAT

Study objectives

Does use of oral microemulsion ciclosporin, followed by azathioprine, in patients admitted to hospital with acute severe ulcerative colitis reduce the need for colectomy in the short term (at six months), and long term (two years)?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised double-blind placebo-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Severe ulcerative colitis

Interventions

Oral microemulsion of ciclosporin (5.5 to 6.5 mg/kg/day twice a day [bd]) or matched placebo. All patients continue to receive intravenous hydrocortisone and other standard medical therapy. At discharge, patients will start treatment with azathioprine (50 mg daily, increasing to 2 mg/kg after two weeks) and a tapering dose of prednisolone.

Updated 30/07/2014: the trial was stopped due to poor recruitment.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Ciclosporin, azathioprine, hydrocortisone, prednisolone

Primary outcome(s)

All Patients Treated disease status at six months, defined as:

Treatment success = no colectomy and remission off steroid therapy

Partial treatment success = symptoms of active disease, or treatment with steroids (oral or

enema)

Treatment failure = colectomy

Key secondary outcome(s)

1. Treatment outcome at two years (All Patients Treated disease status as defined for primary end-point above)
2. Treatment outcome at three months (All Patients Treated disease status as defined for primary outcome above)
3. Treatment response at 7 days (three or fewer non-bloody stools)
4. Time to remission and time to subsequent relapse measured by life table analysis
5. Quality of life at 6 months assessed using the McMaster inflammatory bowel disease questionnaire and EQ-5D scores
6. Overall incidence of adverse events
7. Employment status and amount of sick leave during follow-up
8. Patients valuation of outcome expressed in terms of time trade-off

Completion date

31/05/2011

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

Patients admitted to hospital with severe ulcerative colitis, who have been treated with intravenous corticosteroids for between 48 hours and 5 days, and still fulfil Truelove and Witts criteria for severe colitis.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Positive stool culture for enteric pathogens or Clostridium difficile
2. Cholesterol level below 3 mM
3. Greater than 5 days treatment with intravenous corticosteroids
4. Crohn's disease
5. Bowel perforation, or obstructive symptoms not due substantially to active inflammation
6. Pregnancy or lactation, or inability to take contraception during the trial
7. Treatment with ciclosporin tacrolimus or infliximab in the three months prior to study entry
8. Serious intercurrent infection or other active disease within three months prior to treatment

9. History of concurrent malignancy, or evidence of colonic dysplasia
10. Known human immunodeficiency virus (HIV) infection
11. Toxic dilation of the colon or clinical condition where colectomy is highly likely
12. Significant renal impairment (serum creatinine above 130 uM)
13. Uncontrolled hypertension

Date of first enrolment

01/06/2005

Date of final enrolment

31/05/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Wolfson Digestive Diseases Centre

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

University of Nottingham (UK)

ROR

<https://ror.org/01ee9ar58>

Funder(s)

Funder type

Industry

Funder Name

Novartis Pharmaceuticals UK Ltd (UK) - unconditional block grant (ref: COLO400A 2423)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration