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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	[ ] Prospectively registered [ ] Protocol
Registration date 20/07/2005	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 30/07/2014	**Condition category** Digestive System	[ ] Individual participant data [ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/06/2005

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

Age group
Adult

Sex
Both

Target number of participants
280

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
England

United Kingdom

Study participating centre
Wolfson Digestive Diseases Centre
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
Research Support & Commercialisation Office
University Park
Nottingham
England
United Kingdom
NG7 2RD

Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration