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Controlled Assessment of Salicylate and Azathioprine

Submission date 08/01/2008	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/01/2008	**Overall study status** Stopped	
Last Edited 17/10/2012	**Condition category** Digestive System	

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
A randomised, open study of aminosalicylate withdrawal in patients with ulcerative colitis in established remission on combination treatment of azathioprine (or 6-mercaptopurine) and an aminosalicylate

Acronym
CASA

Study objectives
To investigate whether azathioprine alone is as effective as azathioprine and a 5-aminosalicylic acid (5-ASA) compound in maintaining recently established remission in patients on both drugs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Cambridgeshire 4 Research Ethics Committee (REC) (formerly Eastern MREC) on the 15th September 2005.

Study design
This will be a randomised, open, multi-centre, withdrawal study. There will be two phases: phase 1, the primary outcome measure over one year, and phase 2, ongoing follow-up out to 3 years.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ulcerative colitis

Interventions
Please note that this study was stopped in 2008 due to poor recruitment.

At enrolment patients (already taking azathioprine and a 5-ASA) will have bloods taken and have a sigmoidoscopy to confirm remission. They will then be randomised to:
1. Mono-therapy (i.e. withdraw their existing 5-ASA and take azathioprine only)
2. Dual-therapy (i.e. continue as normal on azathioprine and their existing 5-ASA)

They will remain on their randomised therapy for 12 months, after which the clinician will review their treatment. Patients will be followed up every 3 months by either telephone contact or clinic visit. Their blood results, which are done every 2 - 3 months by routine NHS azathioprine blood monitoring, will be recorded as part of the study. They will also be followed up after 24 months and 36 months by clinic visit.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Azathioprine (or 6-mercaptopurine), 5-aminosalicylic acid

Primary outcome(s)
Relapse rates of azathioprine mono-therapy compared to azathioprine and salicylate dual therapy over the first 12 months.

Key secondary outcome(s))
Factors predictive of success of the different treatment regimes.

Completion date
31/12/2009

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Male and female patients aged between 18 and 75 years with ulcerative colitis
2. Patients whose ulcerative colitis has been in clinical remission, defined as being off steroids for 3 months or longer
3. Patients taking both azathioprine (or 6-mercaptopurine) and an aminosalicylate
4. Patients taking azathioprine (greater than 50 mg/day) or 6-mercaptopurine (greater than 25 mg/day) at a stable dose for at least 8 weeks
5. Patients taking an aminosalicylate at a stable dose (specified below) for at least 4 weeks:
5.1. Sulphasalazine greater than 1.5 g/day
5.2. Pentasa (slow release mesalazine) greater than 750 mg/day
5.3. Asacol (mesalazine) or generic equivalents greater than 800 mg/day
5.4. Colazide (balsalazide) greater than 2.25 g/day
5.5. Dipentum (olsalazine) greater than 750 mg/day
6. Patients on combined treatment with azathioprine (or 6-MP) and an aminosalicylate for a minimum of 6 months but no more than 4 years without relapse. Patients may enter if they have briefly been off either treatment during this time (e.g., because of abnormal blood test results) but prescription of each drug should cover at least 85% of the period of time for continuous drug treatment to be declared. N.B. Duration of aminosalicylate may be longer.
7. Patients who have given written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients with Crohns disease
2. Patients with a baseline Walmsley Simple Activity Index greater than 2
3. Patients with a baseline sigmoidoscopy grade of greater than 2 (Baron Scale)
4. Patients requiring long term treatment with oral steroids for any medical condition
5. Women who are pregnant or lactating
6. Patients with known human immunodeficiency virus (HIV) infection
7. Other serious medical or psychiatric illness currently ongoing, or experienced within the past three months, that in the opinion of the investigator would compromise the study
8. Patients unable to comply with the protocol requirements, including severe alcohol and drug use

Date of first enrolment
01/02/2006

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Division of Epidemiology and Public Health
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Sponsor information

Organisation
University of Nottingham (UK)

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Charity

Funder Name
Moulton Charitable Foundation (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration