

# Controlled Assessment of Salicylate and Azathioprine

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/01/2008	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 17/10/2012	<b>Condition category</b> Digestive System	<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

## Study information

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

**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**

Nottingham

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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