# Randomised controlled trial of mesalazine in symptomatic diverticular disease

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
21/04/2010		☐ Protocol		
Registration date 22/04/2010	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
03/07/2019	Digestive System			

#### Plain English summary of protocol

Background and study aims

Diverticular disease affects two thirds of those over the age of 65 of whom about 1 in 5 will develop symptoms. These consist of abdominal pain and erratic bowel habit. There is as yet no effective treatment for these symptoms and this study aimed to test the idea that an anti-inflammatory drug called Mesalazine might benefit. Preliminary studies suggested possible benefit but this needed confirmation.

#### Who can participate?

Patients with known diverticular disease and recurrent abdominal pain and erratic bowel habit.

#### What does the study involve?

Patients were required to take either Mesalazine or dummy drug (placebo) twice daily for three months. At the beginning of the study, the lower bowel was examined and a small specimen taken from the lining. This was repeated at the end of the study to look at the effect of Mesalazine on the gut lining.

#### What are the possible benefits and risk?

We hoped that abdominal symptoms would improve. The drug has been used for many years and the side effects are well recognised. About 1 in 10 of the patients would not have tolerated the drug but only rarely (less than 1 time in 1000) would there have been serious side effects.

Where is the study run from? Queens Medical Centre, Nottingham (UK)

When is the study starting? August 2008 to January 2011

Who is funding the study? The Wellcome Trust (UK)

Who is the main contact?
Dr Jan Smith
Jan.smith@nottingham.ac.uk

## **Contact information**

## Type(s)

Scientific

#### Contact name

**Prof Robin Spiller** 

#### Contact details

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## Additional identifiers

Clinical Trials Information System (CTIS)

2006-006198-26

ClinicalTrials.gov (NCT)

NCT00663247

Protocol serial number

29856; 086609

## Study information

#### Scientific Title

Mechanistic randomised controlled trial of mesalazine in symptomatic diverticular disease

#### Acronym

SAG44

#### Study objectives

To undertake a pilot mechanistic, two group parallel design, randomised controlled trial of antiinflammatory treatment (mesalazine) in individuals with symptomatic diverticular disease to identify markers to assess the relationship between inflammation and symptoms.

## Ethics approval required

#### Old ethics approval format

#### Ethics approval(s)

Nottingham Regional Ethics Committee 1, 12/10/2007, ref: 07/Q2403/83

#### Study design

Interventional two group parallel randomised double-blinded placebo controlled trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Diverticular disease

#### **Interventions**

Mesalazine 3 g/day for 3 months Placebo 3 g/day for 3 months

Total duration of follow-up is 3 months (12 weeks) in each study arm.

#### Intervention Type

Drug

#### Phase

Phase IV

## Drug/device/biological/vaccine name(s)

Mesalazine

#### Primary outcome(s)

Difference in change in galanin expression in mucosal nerves from 0 to 12 weeks/withdrawal between mesalazine and placebo treated groups.

## Key secondary outcome(s))

Differences between mesalazine and placebo groups with respect of changes from 0 to 12 weeks /withdrawal of:

- 1. Substance P expression in mucosal nerves
- 2. Cell counts of CD3, CD25, CD68 positive cells, neutrophils and Paneth cells
- 3. Faecal calprotectin
- 4. Urine neopterin
- 5. Serum interleukin-8 (IL-8)/interleukin-6 (IL-6)
- 6. Abdominal pain, stool frequency amd mean stool consistency
- 7. Messenger ribonucleic acid (mRNA)/protein expression of inflammatory cytokines

#### Completion date

01/01/2011

# **Eligibility**

#### Key inclusion criteria

- 1. Symptomatic diverticular disease with short lived recurrent abdominal pain on 3 or more days a month
- 2. Aged 18 85 years of age, either sex
- 3. Signed informed consent
- 4. Presence of at least one diverticulum in the left colon

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Key exclusion criteria

- 1. Pregnant or lactating women
- 2. Severe co-morbidity, alcoholism or drug dependence or inability to give informed consent
- 3. Contraindications to use of mesalazine as detailed in summary of product characteristics (SmPC)
- 4. Inability to stop non-steroidal anti-inflammatory drugs (NSAIDs) or long term antibiotics
- 5. The use of specific concomitant medications
- 6. Presence of other gastrointestinal inflammatory conditions such as ulcerative colitis, Crohn's disease and Coeliac disease

#### Date of first enrolment

01/08/2008

#### Date of final enrolment

01/01/2011

## Locations

#### Countries of recruitment

United Kingdom

England

## Study participating centre

#### Nottingham Digestive Disease Centre

School of Medicine
The University of Nottingham
E Floor, West Block, QMC
Nottingham
United Kingdom
NG7 2UH

# Sponsor information

#### Organisation

University of Nottingham (UK)

#### **ROR**

https://ror.org/01ee9ar58

# Funder(s)

#### Funder type

Charity

#### **Funder Name**

Wellcome Trust (grant ref: 086609)

Alternative Name(s)

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

International organizations

#### Location

**United Kingdom** 

## **Results and Publications**

#### Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

#### IPD sharing plan summary

# Other

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	abstract	01/07/2012		No	No
Basic results				No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes