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Randomised controlled trial of mesalazine in symptomatic diverticular disease

Submission date 21/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/04/2010	**Overall study status** Completed	
Last Edited 03/07/2019	**Condition category** 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00663247

Clinical Trials Information System (CTIS)
2006-006198-26

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 anti-inflammatory 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

Primary study design
Interventional

Study design
Interventional two group parallel randomised double-blinded placebo controlled trial

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
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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