Randomised controlled trial of mesalazine in symptomatic diverticular disease

Submission date	Recruitment status No longer recruiting	Prospectively registered		
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

EudraCT/CTIS number

2006-006198-26

IRAS number

ClinicalTrials.gov number

NCT00663247

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/08/2008

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40

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

England

United Kingdom

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)

Sponsor details

c/o Paul Cartledge King's Meadow Campus Lenton Lane Nottingham England United Kingdom NG7 2NR

Sponsor type

University/education

Website

http://www.nottingham.ac.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

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

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?
Basic results				No	No
Abstract results	abstract	01/07/2012		No	No