Double-blind, randomized, placebo-controlled, parallel group, multi-centre phase III clinical study on the efficacy and tolerability of mesalazine granules vs. placebo for the prevention of recurrence of diverticulitis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diverticular disorders
Study type	Interventional

Summary

ID

NL-OMON35257

Source
ToetsingOnline

Brief title
SAG-37/DIV

Condition

- Diverticular disorders

Synonym
diverticulitis; pouch formations of the intestinal wall

Research involving

Human

Sponsors and support

Primary sponsor: Dr. Falk Pharma GmbH
Source(s) of monetary or material Support: Dr. Falk Pharma GmbH;Freiburg;Duitsland

Intervention

Keyword: diverticulitis, mesalazine, recurrence, Salofalk

Outcome measures

Primary outcome

Proportion of recurrence-free patients within 48 weeks: Recurrence of diverticulitis, defined as CRP > ULN or after leucocytosis and recurrence of diverticulitis-like symptoms (left lower quadrant pain, fever) with associated clinical, biochemical parameters or confirmation by ultrasonography or computed tomography

Secondary outcome

Proportion of patients with recurrence,

Time in study,· Time to recurrence,

Time to recurrence or discontinuation,

Subgroup analysis for number of episodes of diverticulitis in the previous year (2 episodes vs more than 2 episodes), Subgroup analysis for prompt vs delayed start of treatment after attack,

Subgroup analysis for inflammatory markers increased vs not increased at baseline,

Course of ESR,

Course of CRP,

Course of leucocytosis,

Occurrence of diverticulitis-associated fever,

Number of days with left lower quadrant pain,

Number of days with stools of solid consistency,

Number of days with stools of soft or solid consistency,

Number of days with diarrhea (> 3 stools per day),

Number of days with stools of watery consistency,

Average frequency of stools per week,

Amount of used spasmolytics,

Amount of used analgesics,

Worsening of symptoms, e.g., use of antibiotics, hospitalization for underlying

disease, surgery,

Quality of life,

Health assessment,

Assessment of efficacy by investigator and patient.

Study description

Background summary

Up to now no evidence based recommendation for the prevention of recurrence of diverticulitis is available. As inflammation appears to play an important role in the course of diverticulitis, mesalazine (an anti-inflammatory drug) might be useful for the treatment and the prevention of recurrence of diverticulitis. A therapeutic effect could be demonstrated in a few studies, however, these studies are not evidence-based. Thus, the aim of this study is to examine the therapeutic effect of mesalazine with state of the art procedures (randomized, double-blind, placebo-controlled, parallel group).

Study objective

The objective of the study is to compare the efficacy and tolerability of mesalazine granules (3 g 5*ASA/d) vs. placebo for the prevention of recurrence of diverticulitis. Additionally, the safety and tolerability in the form of adverse events and laboratory parameters should be studied. Thirdly, the patients* quality of life will be assessed.

Study design

This study is a double-blind, randomised, placebo-controlled, parallel group, multicentre phase III clinical study and is sponsored by Dr. Falk Pharma GmbH, Germany. The study should start approximately in february/march 2008 and should last until approximately mid of 2011.

Intervention

One group of patients will administer 2 sachets of 1.5 g mesalacine granules per day whereas the other group will administer 1.5 g placebo granules per day during the study (48 weeks).

Study burden and risks

The patients are not exposed to a high risk while they are participating in this trial. Mesalazine is widely used for treatment of inflammatory bowel disease. It is already registered in the Netherlands and only few side-effects are observed. Possible side effects are headache, nausea, diarrhea or rash. During this study control examinations and blood tests will be performed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Diagnosis of left-sided uncomplicated diverticular disease confirmed by ultrasonography or computed tomography.
Presence of at least one diverticulum of the left colon.
Most recent attack of left-sided uncomplicated diverticulitis responding to antibiotis and/or dietary modifications within the last 6 months.
3 or more of the following symptoms documented at the start of the most recent attack:
- left lower quadrant pain
- fever (higher than 38°C by rectal measurement)
- altered bowel habit (diarrhea, constipation, passage of mucus, or urgency)
- systemic upset (nausea, lethargy)
CRP > ULN or leucocytosis (> 10 000/mm^3) at the start of the most recent attack

Exclusion criteria

Chronic inflammatory bowel disease.
Complicated diverticular disease (diverticulitis with associated abscess, fistula, obstruction or perforation)
Right-sided diverticulitis.
Presence of symptomatic organic disease of the gastrointestinal tract.
Only patients planned for CT: hyperthyroidism, history of hypersensitivity to iodine or iodinated contrast media, congestive heart failure (NYHA III/IV), multiple myeloma, diabetes with need of drug treatment.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-08-2008
Enrollment:	70
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Salofalk 1.5 g granules
Generic name:	mesalazine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	10-03-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-04-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-02-2009

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-03-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-04-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-000680-22-NL
ClinicalTrials.gov	NCT00695643
CCMO	NL20513.029.08