# Effect of oral lactulose on clinical and immunohistochemical parameters in patients with inflammatory bowel disease: a prospective, randomised and controlled pilot study

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>		
16/11/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
13/12/2006	Completed	[X] Results		
<b>Last Edited</b> 24/09/2009	<b>Condition category</b> Digestive System	[] Individual participant data		

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Prof Stephan C Bischoff

#### Contact details

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# Additional identifiers

**Protocol serial number** N/A

# Study information

#### Scientific Title

#### Acronym

Lactulose

#### Study objectives

Inflammatory bowel diseases (IBD), commonly referred to as Crohns Disease (CD) and Ulcerative Colitis (UC) are recurrent aggressive inflammatory conditions of multifactorial etiology, which to date are not well understood. Interactions of genetic background, disturbance of the mucosal barrier, dysregulation of intestinal immune responses as well as bacterial and other environmental factors were found to play a role in the development of IBD.

#### Aims of trial:

Positive clinical and histological efficacy of lactulose in patients with IBD.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

The study was approved by the Ethical Committee of the Hannover Medical School, dated 7th February 2000 (ref: No 2229). All procedures were in accordance with the Declaration of Helsinki.

#### Study design

Prospective, randomised and controlled pilot study

## Primary study design

Interventional

## Study type(s)

Treatment

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

Inflammatory Bowel Disease (IBD), Crohns Disease (CD), Ulcerative Colitis (UC)

#### **Interventions**

The aim of the present study was to investigate clinical effects of the prebiotic "lactulose" in IBD patients.

#### Intervention Type

Drug

#### Phase

**Not Specified** 

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

Oral lactulose

#### Primary outcome(s)

Improvement of clinical activity

#### Key secondary outcome(s))

- 1. Quality of life
- 2. Medication
- 3. Endoscopic score
- 4. Laboratory parameters:
- a. Haemoglobin (Hb) values
- b. Haematocrit values
- c. Orsomucoid (Ors)
- d. Albumin (Alb)
- e. Immunoglobulins G, A and M (IgG, IgA and IgM respectively)
- f. Alpha-1-antitrypsin
- g. pH in faeces

#### Completion date

01/07/2003

# **Eligibility**

#### Kev inclusion criteria

To be included in the trial, patients had to present IBD. The majority of patients enrolled in this study were hospitalised because of symptoms of active disease and in most of them the clinical activity was confirmed by elevated Clinical Activity Index (CAI) scores in UC or elevated Crohns Disease Activity Index (CDAI) scores. The diagnosis of IBD was confirmed by classical clinical and endoscopic means according to the German and Austrian guidelines for UC and CD.

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

**Not Specified** 

#### Sex

Αll

#### Key exclusion criteria

- 1. Surgery during study period
- 2. Other diseases than IBD

#### Date of first enrolment

01/08/2000

#### Date of final enrolment

01/07/2003

# Locations

#### Countries of recruitment

Study participating centre University of Hohenheim Stuttgart Germany 70599

# Sponsor information

#### Organisation

Solvay Pharmaceuticals GmbH (Germany)

#### **ROR**

https://ror.org/01xscrc43

# Funder(s)

## Funder type

Industry

#### **Funder Name**

Funding was supplied by Solvay Pharmaceuticals GmbH, which covered expenses for drugs and equipment (Germany)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/09/2007		Yes	No