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

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### 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 measure
Improvement of clinical activity

### Secondary outcome measures
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

### Overall study start date
01/08/2000

### Completion date
01/07/2003

## Eligibility

### Key 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

### Age group
Not Specified

**Sex**
Both

**Target number of participants**
70

**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**
Germany

**Study participating centre**
**University of Hohenheim**
Stuttgart
Germany
70599

# Sponsor information

**Organisation**
Solvay Pharmaceuticals GmbH (Germany)

**Sponsor details**
Hans-Böckler-Allee 20
Hannover
Germany
30173

**Sponsor type**
Industry

**Website**
http://www.solvay.de/

**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

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**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 |