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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

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