

High fibre diet and low dose lincomycin for chronic constipation

Submission date 13/01/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 16/02/2011	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 16/02/2011	Condition category Digestive System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A controlled pilot study on the efficacy of a high fibre diet and a low dose lincomycin for chronic constipation

Study objectives

Assess the synergistic short term, low dose, preparatory action of a poorly absorbable antibiotic on chronic constipated patients on a high fibre diet.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This was a very small pilot observational study started in 1996 and finalised 1 year later. At the time of this pilot study, there was an exogenous improvised board named simply by the principal investigator and the ethics board that met gave only verbal approval. Since then, this board has dissolved and unfortunately records are not available.

Study design

Randomised double-blind placebo controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic constipation

Interventions

The study design determined a 15-day run-in phase without any drug or rescue laxatives and a 21-day controlled treatment period. On the first day of the controlled treatments period (Day 0) enrolled patients were randomised to an initial 10 day low dose lincomycin (0.5 g/d) or to placebo. During the 21 day treatment period, the diet of all patients was supplemented by 12 g of crude fibre (All Bran Kellog).

Patients were assigned a number on accordance to a validated 10 point Visual Analogue Scale (VAS) of symptom severity (0 = very severe, 10 = asymptomatic). Post-hoc, we examined the proportion of patients that exhibited marked improvement in the efficacy parameters after the 21 day treatments.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Lincomycin

Primary outcome(s)

Difference between treatments in the mean bowel frequency, straining, stool consistency and pain during defecation at baseline (Day 0) and by the end of treatment period (Day 21).

Key secondary outcome(s)

No secondary outcome measures

Completion date

15/04/1997

Eligibility

Key inclusion criteria

1. Meet Rome II diagnostic criteria for chronic constipation characterised by:
 - 1.1. A frequency of less than or equal to two bowel movements/week
 - 1.2. Hard stool
 - 1.3. Straining with occasional pain in more than 25% of bowel movements
2. Aged over 18 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Cardiac, pulmonary, renal, liver failure
2. Abnormal blood chemistries
3. Known antibiotic allergies

In patients who were younger than 50 years and had no other complaint than chronic constipation and the physical examination and routine body chemistries were normal, it was assumed the diagnostic of functional constipation and no special gastrointestinal exams were performed. Patients greater than or equal to 50 years or with lower gastrointestinal bleeding underwent colon radiology or colonoscopy to rule out organic colorectal disease.

Date of first enrolment

05/09/1996

Date of final enrolment

15/04/1997

Locations

Countries of recruitment

Argentina

Study participating centre

Echeverria 2771

CABA

Argentina

1428

Sponsor information

Organisation

Institute of Gastroenterology (Instituto de Gastroenterologia) (Argentina)

Funder(s)

Funder type

Research organisation

Funder Name

Institute of Gastroenterology (Instituto de Gastroenterologia) (Argentina)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration