ISRCTN33023013 https://doi.org/10.1186/ISRCTN33023013

# High fibre diet and low dose lincomycin for chronic constipation

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 13/01/2011 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 16/02/2011 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 16/02/2011 | Digestive System | [ ] 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet

## 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 measure
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).

### Secondary outcome measures
No secondary outcome measures

### Overall study start date
05/09/1996

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
30 patients

### 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)

### Sponsor details
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### Sponsor type
Research organisation

## Funder(s)

### Funder type
Research organisation

### Funder Name

Institute of Gastroenterology (Instituto de Gastroenterologia) (Argentina)

# 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