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

Contact name
Dr Luis Maria Bustos Fernandez

Contact details
Echeverria 2771
CABA
Argentina
1428
lbustos@arnetbiz.com.ar

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
Echeverria 2771
CABA
Argentina
1428
lbusto@arnetbiz.com.ar

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