

Effects of probiotics on liver function in chronic liver disease

Submission date 25/10/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 11/11/2009	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 11/11/2009	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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2031

Additional identifiers

Protocol serial number
00/207

Study information

Scientific Title
Effects of probiotics on liver function in chronic liver disease: a randomised controlled trial

Study objectives
Probiotic treatment may improve liver function in patients with cirrhosis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South Eastern Illawarra Area Health Service approved on the 5th July 2002 (ref: 00/215)

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cirrhosis

Interventions

Oral probiotic or placebo therapy for 30 days

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Markers of liver function, measured at day 7, day 28 and day 56.

Key secondary outcome(s)

Tolerability, measured at day 7, day 28 and day 56.

Completion date

01/10/2010

Eligibility**Key inclusion criteria**

1. Patients aged between 18 and 70 years (either sex) with established cirrhosis
2. No antibiotic or lactulose therapy within 6 weeks
3. No prior use of probiotic therapy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Age under 18 years or over 70 years
2. Antibiotic or lactulose therapy within 6 weeks
3. Prior use of probiotic therapy
4. Hepatocellular carcinoma

Date of first enrolment

01/10/2009

Date of final enrolment

01/10/2010

Locations

Countries of recruitment

Australia

Study participating centre

The Prince of Wales Hospital

Randwick

Australia

2031

Sponsor information

Organisation

The Prince of Wales Hospital (Australia)

ROR

<https://ror.org/022arq532>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (Australia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration