

Effects of probiotics on liver function in chronic liver disease

Submission date 25/10/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/11/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/11/2009	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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2031

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/10/2009

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

30

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)

Sponsor details

c/o Professor Stephen Riordan
Blacket Building
Barker Street
Randwick
Australia
2031

Sponsor type

Hospital/treatment centre

ROR

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

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (Australia)

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