ISRCTN50009946 https://doi.org/10.1186/ISRCTN50009946

Effects of probiotics on liver function in chronic liver disease

Submission date	Recruitment status	[ ] Prospectively registered
25/10/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/11/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/11/2009	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
Prof Stephen Riordan

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The Prince of Wales Hospital
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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