Prospective randomised controlled study to evaluate the role of synbiotic cocktail 2000 before, during and after liver transplantation to increase resistance to infection

Submission date 12/09/2003	Recruitment status Stopped	 Prospectively registered Protocol
Registration date 12/09/2003	Overall study status Stopped	 Statistical analysis plan Results
Last Edited 24/05/2012	Condition category Surgery	 Individual participant data Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name Prof Brian R Davidson

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0256114034

Study information

Scientific Title

Study objectives Whether giving pre and probiotics could decrease the incidence of infective complications in patients having liver transplantation.

Ethics approval required Old ethics approval format

Ethics approval(s) Not provided at time of registration

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 Surgery: Liver transplant

Interventions Prospective randomised controlled trial.

Intervention Type Procedure/Surgery

Phase Not Specified

Primary outcome measure

Service outcomes development.

Secondary outcome measures Not provided at time of registration

Overall study start date 22/07/2002

Completion date 01/06/2004

Reason abandoned (if study stopped) Lack of funding

Eligibility

Key inclusion criteria 120 Patients and 40 controls.

Participant type(s) Patient

Age group Not Specified

Sex Not Specified

Target number of participants 160

Key exclusion criteria Does not match inclusion criteria

Date of first enrolment 22/07/2002

Date of final enrolment 01/06/2004

Locations

Countries of recruitment England

United Kingdom

Study participating centre

University Department of Surgery London United Kingdom NW3 2QG

Sponsor information

Organisation Department of Health (UK)

Sponsor details Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type Government

Website http://www.doh.gov.uk

Funder(s)

Funder type Hospital/treatment centre

Funder Name The Royal Free Hampstead NHS Trust (UK)

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