

Efficacy of Consuming LcS In Spinal cord injury Patients (ECLISP)

Submission date 08/01/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/03/2024	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Probiotics, defined as 'live microorganisms which, when administered in adequate amounts, confer a health benefit on the host', have been proposed to help maintain a healthy gut microbiota in hospitalised patients on antibiotic therapy, particularly those on broad spectrum antibiotics. It is hypothesised that maintenance of a healthy commensal microbiota during antibiotic treatment by taking a probiotic every day will significantly reduce the occurrence of antibiotic associated diarrhoea (AAD) and Clostridium difficile associated diarrhoea (CDAD), improving the quality of life in spinal cord injury patients over time. A previous trial in patients with spinal cord injuries (SCI) suggests that probiotics can prevent antibiotic associated diarrhoea (AAD). A number of studies have reported that Yakult (Lactobacillus casei Shirota) can help reduce antibiotic-associated diarrhoea. However, in order to confirm these effects find out how well Lactobacillus casei Shirota (LcS) works in these patients, a larger study including different geographical locations should be carried out.

Who can participate?

Adults (aged at least 18), likely to remain at the Spinal Cord Injury Centre (SCIC) for more than 6 weeks and have been taking antibiotics for at least 3 days.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 are given one bottle of Yakult containing 6.5×10^9 Lactobacillus casei Shirota once a day during the course of antibiotics and for 7 days after the course finishes. Those in group 2 are given a placebo. All participants are monitored for occurrence of AAD and CDAD. Gastrointestinal microbiota are also measured and also an assessment of quality of life.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Stoke Mandeville Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2014 to October 2017

Who is funding the study?
Yakult Honsha Co., Ltd

Who is the main contact?
Mr Edmund Chiu

Contact information

Type(s)
Scientific

Contact name
Mr Edmund Chiu

Contact details
Stoke Mandeville Hospital
National Spinal Injury Centre
Mandeville Road
Aylesbury
United Kingdom
HP21 8AL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17618

Study information

Scientific Title
Effect of Lactobacillus casei Shirota in preventing antibiotic associated diarrhoea (AAD) including Clostridium difficile associated diarrhoea (CDAD) in patients with spinal cord injuries: a multicentre, randomised, double-blind, placebo-controlled trial

Acronym
ECLISP

Study objectives

It is hypothesised that maintenance of a healthy commensal microbiota during antibiotic treatment by administration of a daily probiotic (*Lactobacillus casei* Shirota, as Yakult) will significantly reduce the occurrence of AAD and CDAD, and thus improve quality of life in spinal cord injury patients over time in comparison to the placebo control.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Oxford REC, 25/09/2014, 14/SC/1101

Study design

Randomised; Interventional; Design type: Treatment

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

Antibiotic associated/*Clostridium difficile* diarrhoea

Interventions

Lactobacillus casei Shirota. One bottle of Yakult containing 6.5×10^9 *Lactobacillus casei* Shirota once a day during the course of antibiotics and for 7 days after the course finishes.

Intervention Type

Supplement

Primary outcome measure

Occurrence of antibiotic-associated diarrhoea: Timepoint(s): 30 days

Secondary outcome measures

Analyse the effect of LcS on:

1. Occurrence of *C. difficile* diarrhoea
2. Duration of diarrhoea
3. Gastrointestinal microbiota
4. Quality of life

Measured 30 days after finishing probiotic/placebo.

Overall study start date

12/11/2014

Completion date

31/10/2017

Eligibility

Key inclusion criteria

1. Adult (≥ 18 years)
2. Patient is likely to remain in the Spinal Cord Injury Centre (SCIC) for more than 6 weeks can be included
3. Newly started antibiotics (for a minimum of 3 days) (single or multiple)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 360; UK Sample Size: 360

Total final enrolment

359

Key exclusion criteria

1. Re-recruit patient (1st recruitment only)
2. Antibiotics for prophylaxis use
3. Diarrhoea prior to recruitment
4. Bowel pathology that could result in diarrhoea
5. Recent bowel surgery
6. Infective endocarditis
7. Active inflammatory bowel disease
8. Pancreatitis
9. Regular probiotic use
10. Antibiotic use in the 30 days prior to the study product first administration
11. Severe illness
12. Immunosuppression
13. Nil-by-mouth status for any reason
14. Nonfunctioning gut
15. Known cows milk protein intolerance

- 16. Psychiatric or cognitive conditions that may interfere with the study
- 17. Patients incapable of providing informed consent
- 18. Patients unlikely to comply with study requirements
- 19. Pregnant or breastfeeding women
- 20. Prisoners

Date of first enrolment

12/11/2014

Date of final enrolment

31/10/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Stoke Mandeville Hospital

National Spinal Injury Centre

Mandeville Road

Aylesbury

United Kingdom

HP21 8AL

Sponsor information

Organisation

Buckinghamshire Healthcare NHS Trust

Sponsor details

Department of R&D

Stoke Mandeville Hospital

Mandeville Road

Aylesbury

England

United Kingdom

HP21 8AL

Sponsor type

Hospital/treatment centre

ROR

Funder(s)

Funder type
Industry

Funder Name
Yakult Honsha Co., Ltd

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/09/2021	21/09/2021	Yes	No
HRA research summary			26/07/2023	No	No
Results article		22/03/2024	25/03/2024	Yes	No