

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

<b>Submission date</b> 08/01/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/01/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/03/2024	<b>Condition category</b> 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  $6.5 \times 10^9$  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

### Protocol serial number

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)

**Study design**

Randomised; Interventional; Design type: Treatment

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Antibiotic associated/Clostridium difficile diarrhoea

**Interventions**

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

**Intervention Type**

Supplement

**Primary outcome(s)**

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

**Key secondary outcome(s)**

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.

**Completion date**

31/10/2017

**Eligibility****Key inclusion criteria**

1. Adult ( $\geq 18$  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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

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

## Sponsor information

**Organisation**  
Buckinghamshire Healthcare NHS Trust

**ROR**  
<https://ror.org/037f2xv36>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Yakult Honsha Co., Ltd

## Results and Publications

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?
<a href="#">Results article</a>	results	11/09/2021	21/09/2021	Yes	No
<a href="#">Results article</a>		22/03/2024	25/03/2024	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes