

# A randomised controlled trial of VSL#3 for the prevention of endoscopic recurrence following surgery for Crohn's disease

<b>Submission date</b> 18/11/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/11/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/04/2019	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Richard Neil Fedorak

### Contact details

Director  
Division of Gastroenterology  
University of Alberta  
Suite 205 College Plaza  
8215 - 112 Street  
Edmonton  
Canada  
T6G 2C8

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00175292

## Secondary identifying numbers

UCT-52194

# Study information

## Scientific Title

A randomised controlled trial of VSL#3 for the prevention of endoscopic recurrence following surgery for Crohn's disease

## Study objectives

To determine the efficacy of the probiotic VSL#3 in the prevention of Crohns disease development following surgical resection and re-anastomosis.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The Health Research Ethics Board (Biomedical Panel) of the University of Alberta, Edmonton, Alberta, gave approval on the 22nd June 2001

## 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

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

Crohns Disease/Inflammatory Bowel Disease

## Interventions

A randomised controlled trial of VSL#3 versus placebo

Trial details received 12 Sept 2005

## Intervention Type

Other

## Phase

Not Applicable

## **Primary outcome measure**

To assess the efficacy of VSL#3 for the prevention of severe endoscopic recurrence (Rutgeerts Grade three or four) of Crohns disease, within 90 days of study treatment, in patients who have undergone an ileocolonic resection with small intestine to colonic anastomosis

## **Secondary outcome measures**

1. To assess the efficacy of VSL#3 to prevent all endoscopic recurrence of Crohns disease (Rutgeerts Grades one to four) within 90 days of study treatment
2. Determine the proportion of patients who require medical therapy for management of recurrent Crohns disease within 90 days of study treatment
3. To compare the time to severe endoscopic recurrence of Crohns disease (Rutgeerts endoscopic grade three or grade four) in subjects who receive immediate (within 30 days post resection) versus delayed (more than 90 days post resection) introduction of VSL#3 as maintenance therapy
4. To determine the proportion of patients who require medical therapy for management of their recurrent Crohns disease within 365 days of study treatment
5. To compare the treatments for overall Crohns disease activity as measured by the Crohns disease activity index (CDAI)
6. To compare the treatment for disease specific quality of life endpoints as measured by the inflammatory bowel disease questionnaire (IBDQ)
7. To assess the safety and tolerance of VSL#3
8. To determine:
  - 8.1. The quantity and type of bacterial colonisation
  - 8.2. Mucosal cytokine levels
  - 8.3. Histologic injury
  - 8.4. Mucosal metalloproteinase activity at the neo-terminal ileum and serum cytokine genotyping

These studies will be conducted at a subset of participating centres in Canada.

## **Overall study start date**

01/01/2002

## **Completion date**

31/12/2012

# **Eligibility**

## **Key inclusion criteria**

1. Subjects who are 16 years of age or older
2. Have a diagnosis of Crohns disease of at least three months duration, prior to ileocolonic resection, and the diagnosis is confirmed by radiological studies or endoscopy with biopsy or surgical pathology
3. Resection of ileocolonic Crohns disease, with margins macroscopically free of disease, and small bowel to colonic anastomosis no more than 30 days prior to randomisation
4. Females of child-bearing potential (have not had tubal ligation, hysterectomy or other surgical procedure for sterilisation) must have a negative urine or serum pregnancy test within one week of entry into the study and agree to use an acceptable method for contraception throughout the trial. Acceptable methods of contraception include oral contraceptives, implantable contraceptives, injectable contraceptives, intrauterine device or barrier methods (diaphragm with spermicidal gel plus condoms, condoms with contraceptive sponges, condom plus

intravaginal suppository).

5. Voluntarily able to provide informed written consent

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

120

**Key exclusion criteria**

1. Use of other medications for the treatment of Crohns disease following surgical resection (perioperative steroids in tapering doses and antidiarrhoeal agents - codeine, loperamide, diphenoxylate or cholestyramine are acceptable)
2. Treatment with a tumour necrotising factor (TNF)-antagonist in the eight weeks prior to resection
3. Clinically significant Crohns disease elsewhere in the gastrointestinal tract
4. Clinically documented short bowel syndrome (greater than 100 cm of small bowel resected)
5. Serious underlying disease other than Crohns disease
6. Significantly impaired liver or renal function
7. History of cancer with less than two years in a documented disease-free state (other than resected cutaneous basal and squamous cell carcinoma and or in situ cervical cancer)
8. Patients with the following laboratory abnormalities:
  - 8.1. White blood count less than  $3 \times 10^9/l$
  - 8.2. Lymphocyte count less than  $0.5 \times 10^9/l$
  - 8.3. Haemoglobin less than 80 g/dl
  - 8.4. Platelet count less than  $125 \times 10^9/l$  or more than  $800 \times 10^9/l$
  - 8.5. Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) more than 2.0 times the upper limit of normal
  - 8.6. Alkaline phosphatase more than 2.0 times the upper limit of normal
  - 8.7. Serum Creatinine more than 1.5 times the upper limit of normal
9. Patients using ethanol or consuming illicit drugs which, in the investigators opinion, may interfere with compliance with the study procedures
10. Patients with active psychiatric problems, which, in the investigators opinion, may interfere with compliance with the study procedures
11. Patients using concomitant investigational therapy
12. Patients who are unable to attend study visits or comply with study procedures

**Date of first enrolment**

01/01/2002

**Date of final enrolment**

31/12/2012

**Locations**

**Countries of recruitment**

Canada

**Study participating centre****Director**

Edmonton

Canada

T6G 2C8

## **Sponsor information**

**Organisation**

University of Alberta (Canada)

**Sponsor details**

1A University Campus N.W.

1-05 Assinaboia Hall

Edmonton

Canada

T6G 2E1

**Sponsor type**

University/education

**Website**

<http://www.ualberta.ca/>

**ROR**

<https://ror.org/0160cpw27>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Canadian Institutes of Health Research (ref: UCT-52194)

**Alternative Name(s)**

Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR\_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Canada

## 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?
<a href="#">Results article</a>	results	01/05/2015	19/02/2019	Yes	No