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

Submission date 18/11/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/11/2005	**Overall study status** Completed	
Last Edited 11/04/2019	**Condition category** Digestive System	

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

ClinicalTrials.gov (NCT)
NCT00175292

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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 x 10^9/l
8.2. Lymphocyte count less than 0.5 x 10^9/l
8.3. Haemoglobin less than 80 g/dl
8.4. Platelet count less than 125 x 10^9/l or more than 800 x 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)

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 - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2015	19/02/2019	Yes	No