



RACP Foundation Research Awards

FINAL REPORT

Project / Program Title	Lyophilised orally administered FMT in the management of Ulcerative Colitis (LOTUS study)	
Name	Dr Craig Haifer	
Award Received	2019 Research Entry Scholarship	
Report Date	May 2021	
Chief Investigator / Supervisor	Dr Rupert Leong	
Administering Institution	The University of Sydney	
Funding Period	Start Date:	Feb 2019
	Finish Date:	Feb 2020

PROJECT SUMMARY

This research scholarship allowed me to commence and my doctoral thesis in assessing the role of faecal microbiota transplantation (FMT) in gastrointestinal diseases. FMT is the process of transferring the ecosystem from a gastrointestinal tract from a healthy individual to someone with disease in order to treat the underlying disease process.

At the start of the project, FMT was considered an unapproved therapeutic goods and was governed by individual providers, which severely limited access of this important therapy to most patients.

We initially developed consensus guidelines for its use in Australia and worked with the Therapeutic Goods Administration to develop a regulatory framework. This then paved the way in order to test freeze dried FMT capsules in its use in various gastrointestinal diseases including C.difficile infection and ulcerative colitis.

PROJECT AIMS / OBJECTIVES

Our aim was to further explore the use of FMT in gastrointestinal diseases and to further develop the technique by assessing the use of freeze-dried capsules which would improve the accessibility and feasibility of therapy.

SIGNIFICANCE AND OUTCOMES

Our research showed that lyophilised FMT is associated with long term clinical and microbial improvement in those patients with primary and recurrent C.difficile infection.

In our randomised control trial using FMT in ulcerative colitis, our preliminary results show that lyophilised FMT is safe and effective in the management of ulcerative colitis. Our longer term maintenance withdrawal study was the first study assess the long term use of and continued therapy and shows significant promise.

We will use the outputs of this study to assess the microbial impacts of FMT on the development and progression of ulcerative colitis.

We have used these results as a basis for further funding application to progress our research in using FMT in the maintenance of remission of UC and developing next generation therapy.

PUBLICATIONS / PRESENTATIONS

- Haifer C, Paramsothy S, Borody TJ, Clancy A, Leong RW, Kaakoush N.

Orally administered lyophilised faecal microbiota transplantation in primary and recurrent Clostridioides difficile infection -Long term clinical outcomes and correlation with bacterial and fungal dynamics in a prospective cohort. mSystems Feb 2021 6 (1) e00905-20

- Haifer C, Saikal A, Paramsothy R, Kaakoush NO, Leong RW, Borody TJ,

Kmm MA, Paramsothy S. Response to Faecal Microbiota

Transplantation in Ulcerative Colitis is not sustained long-term

following induction therapy. Gut 2020 Dec 10;gutjnl-2020-323581

- Haifer C, Leong RW, Paramsothy S. The Role of Fecal Microbiota

Transplantation in the Treatment of Inflammatory Bowel Disease. Curr Opin Pharmacol. 2020 Dec; 55: 8-16.

-Haifer C, Kelly CR, Paramsothy S, Andresen D, Papanicolas L, Mckew G, et al. Australian consensus statements for the regulation, production and use of faecal micro biota transplantation in clinical practice. Gut 2020. May;69(5):801-810.

Abstracts:

- Haifer C, Saikal A, Paramsothy S, Borody TJ, Ghaly S, Kaakoush NO, Leong RW.

Lyophilised orally administered faecal microbiota

transplantation for active ulcerative colitis (LOTUS study).

Lecture presentation+ Y-ECCO Best Abstract Award at European

Crohn's and Colitis Organisation Week; July 2021

- Haifer C, Saikal A, Paramsothy S et al. Lyophilised orally

administered fecal microbiota transplantation in the

management of ulcerative colitis (LOTUS study) -results from

the induction phase of a randomised controlled trial. Lecture

presentation, Digestive Diseases Week, May 2021 (upcoming)

- Haifer C, Saikal A, Paramsothy S et al. Lyophilised orally

administered fecal microbiota transplantation in the

management of ulcerative colitis (LOTUS study) -results from the induction phase of a randomised controlled trial. Lecture presentation, Australian Gastroenterology Week, November 2020

(Young Investigator Award, Peoples Choice Award)

- Haifer C, Kelly CR, Paramsothy S, et al Consensus Guidelines for the Regulation, Production and Use of Fecal Microbiota

Transplantation in Clinical Practice. Abstract, Digestive Diseases Week; Chicago, May 2020

- Haifer C, Paramsothy S, Borody TJ, Clancy A, Leong RW, Kaakoush N. Orally administered lyophilized Fecal Microbiota Transplantation in Clostridioides difficile infection -Long term clinical and microbiological outcomes Abstract, Digestive Diseases Week; Chicago, May 2020
-(Poster of Distinction)