Colonoscopy Manual

Trial Title:	A randomised, multi-centre, biomarker-stratified, open-label trial in patients newly diagnosed with Crohn's disease.
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Chief Investigator:	Dr Miles Parkes Department of Gastroenterology, Box 201A Cambridge University Hospitals Cambridge Biomedical Campus Cambridge CB2 0QQ
Telephone:	01223 245 151
Trial Sponsor:	Cambridge University Hospitals NHS Foundation Trust & the University of Cambridge
Co-ordinator:	Mr Francis Dowling Tel: 01223 254 666 Email: francis.dowling@addenbrookes.nhs.uk

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1 Introduction

Ileocolonoscopy for the PROFILE trial will be performed using standard bowel preparation and conscious sedation.

The index diagnostic colonoscopy and week 48 colonoscopy should be video recorded on withdrawal only.

Appropriate trust consent should be obtained to enable retrospective collection of the screening endoscopy video/images (NB many hospitals consent forms allow recording for research & teaching purposes; if this is not a pre-specified option then in patients who you suspect have Crohn's you could add it to the free-text part of the form i.e. 'colonoscopy and video recording for research and teaching'; alternatively have this option added to your consent forms).

The baseline and week 48 videos will be scored using the SES-CD by both local investigators and a central reader.

2 Colonoscopy Procedure

2.1 Preparation for the Colonoscopy

Bowel cleansing should be carried out according to local guidelines.

Each ileocolonoscopy should be done with the best locally available endoscope.

2.2 Performing the Colonoscopy

The procedure will be carried out as per local practice.

The only difference will be ensuring test video is taken prior to procedure and then video recording as well as images taken on withdrawal.

3 Recording the Procedure

3.1 Test Video

A test video should be taken before the first recording. The purpose of the test video is only to ensure that video capture is working correctly and that the endoscopy team are comfortable with the process.

The test video should consist of the following:

A short video (~10 seconds) with an endoscope recording.

This file should then be played back to ensure the video recording works correctly.

This test video does not need to be saved once the play back has been confirmed.

3.2 Image Collection

Photos should be taken on endoscope withdrawal from the following, where possible:

- terminal ileum
- right colon
- transverse colon
- left colon
- sigmoid colon
- rectum

3.3 Required colonoscopy findings

The following data should be recorded in the endoscopy report (hospital records) as source data and transferred to the CRF.

- What was the maximum point of insertion?
  - Terminal ileum, OR caecum OR other (specify site).
- Using the timer clock on your endoscopy monitor / screen please record the following transitions on withdrawal:
  - Time recording started
  - Time from ileum to caecum
  - Time from right colon to transverse colon
  - Time from transverse colon to left colon
  - Time from left colon to rectum
- Predominant disease location?
  - Ileal OR colonic OR ileal & colonic.
- Global severity score?
  - Mild OR moderate OR severe OR quiescent.
- Was there evidence of a fixed stricture which impeded scope progress?
  - If there was a stricture, where was it present? Anal canal OR colon OR ileocaecal valve.
  - If colonic stricture, where was it present? Right colon OR transverse colon OR left colon OR rectum.
- SES-CD total and breakdown scores to be entered (as highlighted in section 4).

4 SES-CD Scoring

Once video capture is completed and the video and images saved, the endoscopist should score the colonoscopy using the Simple Endoscopic Score for Crohn's Disease (SES-CD).

SES-CD scoring (including score for each subsection) should be included in the participants' medical records (e.g. print table below and staple it to the report that gets filed in patient notes).

4.1 SES-CD Scoring

Descriptors for scoring segments are as follows:

	0	1	2	3
Size of ulcers (cm)	None	Aphthous ulcers (diameter 0.1-0.5)	Large ulcers (diameter 0.5-2)	Very large ulcers (diameter >2)
Extent of ulceration	None	<10%	10-30%	>30%
Extent of affected surface	Unaffected segment	<50%	50-75%	> 75%
Presence of strictures	None	Single, can be passed	Multiple, can be passed	Cannot be passed

Please score segments using this table below:

	Ileum	Right colon	Transverse colon	Left colon	Rectum	Total
Presence and size of ulcers						
Extent of ulceration						
Extent of affected surface						
Presence and type of strictures						
					Total	

5 Data Collection

Members of the PROFILE trial team or monitors will visit the study site at regular intervals and will collect anonymised data from the supplied USB encrypted memory stick for central storage.

All recordings must only be identified using the participant's study ID number, and must have the date of colonoscopy recorded.

Videos and/or photo images will then be used for central reading.