

Study documents

Nathan Constantine-Cooke PREdiCCt Trial Steering Committee
PREdiCCt Analytical Committee

Table of contents

| | |
|---|---|
| Introduction | 1 |
| Study protocol | 1 |
| Statistical analysis plans (SAPs) | 2 |
| Baseline analyses | 2 |
| Longitudinal analyses | 2 |
| SAP ammendment | 2 |

Introduction

This page provides key study documents, the study protocol and statistical analysis plans (SAPs), for the PREdiCCt study. These files can either be viewed in the web browser (on computers) or downloaded as PDFs (on both computers and mobile devices).

All documents were initially devised prior to the start of the study, with amendments made during recruitment.

Study protocol

The study protocol is a detailed plan outlining how research will be conducted, providing study objectives, design, methodology, and overall organisation.

Statistical analysis plans (SAPs)

A SAP outlines the statistical methods which will be used in a study. For PREdiCCt, two SAPs were written: one covering baseline analyses and another covering longitudinal analyses.

Where possible, we have tried to closely follow the SAPs. However, due to unexpected developments, the actual analyses performed sometimes differed.

Baseline analyses

The baseline analysis is largely concerned with descriptive analyses of the cohort and exploring associations between baseline characteristics and faecal calprotectin at recruitment. The [baseline section](#) of this website is governed by this SAP.

Longitudinal analyses

The longitudinal analysis consists of survival analyses modelling the time to patient-reported or hard flare. The [time to flare section](#) of this website is governed by this SAP.

SAP ammendment

This document acts as a time stamped amendment to the SAP. Produced as a result of the peer review process for PREdiCCt. Whilst the outcomes (time-to-flare) are unchanged, this amendment clarifies the core dietary dataset and outlines additional sensitivity analyses.