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[1] **Type**: Use one of the following codes (in consistence with the Description of the Action):
R: Document, report (excluding the periodic and final reports)
DEM: Demonstrator, pilot, prototype, plan designs
DEC: Websites, patents filing, press & media actions, videos, etc.

[2] **Dissemination level**: Use one of the following codes (in consistence with the Description of the Action)
PU: Public, fully open, e.g. web
SEN: Sensitive, limited under conditions of the Grant Agreement

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Summary

This report gives overview of the current status of recruitment for the clinical study conducted by UKE. Based on prior experiences, time for patient recruitment, follow-up assessments and data analysis are chosen with care. In this context, particularly the recruitment of 20 participants per group at the outpatient clinics at the UKE were estimated as feasible.

1 Introduction

The objective of this clinical study is to demonstrate efficacy and feasibility of a long-term dietary intervention to modify intestinal inflammation in inflammatory bowel disease (IBD) patient cohorts. To this end we will investigate a 1.5-year wheat protein-free diet in patients with IBD with and without associated primary sclerosing cholangitis (PSC). A 78-week dietary intervention will be administered to patients with ulcerative colitis (UC, n=20), crohn´s disease (CD, n=20) and UC patients with associated PSC (PSC-IBD, n=20).

2 Patient recruitment numbers as of 15/12/2023

The midterm recruitment report was scheduled for the time point when 50% of the study population were expected to have been recruited for this clinical study. Ethics approval was received in time and study recruitment has fulfilled expectations.

Prescreening of the UKE outpatient PSC-IBD cohort had started in advance to finalization of study registration and processes of the clinical study were practiced and evaluated in a pilot phase during the first quarter of 2023. A total of 130 patients of the PSC-IBD patients were identified and contacted as potential study participants. For UC and CD cohorts the prescreening started after study registration in the third quarter of 2023 and a total of 50 patients (UC and CD) were identified as potential study participants.

As of the 15th of December 2023, 20 study participants have been included (see figure 1). To avoid additional endoscopy procedures, integration of prevention colonoscopy is aimed for all study participants, and therefore timepoints for study inclusion and first study colonoscopies (pre intervention) are aligned. Taken this into account, 10 more study participants have been positively screened and are scheduled for study inclusion for the first or second quarter of 2024. The latter

included, 50% of the proposed study participants have been positively screened or included into the clinical study so far.

Two more study participants had to be excluded after screening visit / respectively first colonoscopy. One patient was newly diagnosed with celiac disease. Another patient showed surprisingly severe intestinal inflammation with need for direct change of biological treatment. One female patient had to be excluded after the 3 month visit due to pregnancy.

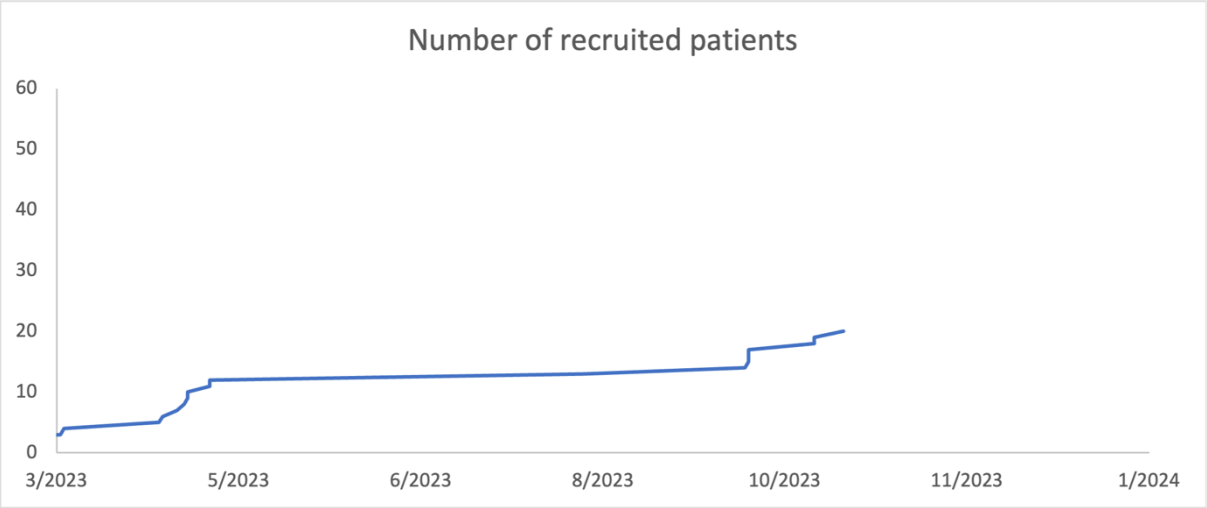


Figure 1: Recruitment number for the WP2 clinical study from Q1 to present.

Patient cohort	Patients recruited as of 15/12/2023	Patient recruitment was started
PSC-IBD	14	Q1/Q2 2023
UC	3	Q3/O4 2023
CD	3	Q3/O4 2023

Table 1: Patient recruitment per group.

3 Future patient recruitment

Assuming similar recruitment rates as previously achieved, the recruitment target of 60 study participants (20 per cohort) by Q3 of 2024 is expected to be achieved (last patient out Q1 of 2026). Intensive prescreening will be performed at the UKE outpatient clinic for IBD patients and referring local gastroenterologists. Considering a rate of 15% at prescreening, 200 more study participants have to be identified and evaluated for a potential study participation. UKE outpatient clinic takes care for more than 150 IBD patients per month, therefore a prescreening number of 200 individuals appears feasible within the next 9 months.

With regard to the critical risk identified in the proposal stage, *High dropout rate of patients from dietary intervention (LT-GFD) study*, UKE is paying special attention to its mitigation. Trained nutritional experts are offering support and providing critical information to the patients throughout the process, and study administrators are keeping track of various forms of contact with patients, reaching out more frequently to patients who are less responsive.

4 Conclusion

In total 50% of the proposed study population, 30 of 60 patients have been positively screened or included into the clinical study. It is expected, that the recruitment target of 60 patients will be reached in the third quarter of 2024.