

MEDIRAD

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Midterm recruitment report

Lead partner: UMR

Author(s): Jan Taprogge, Glenn Flux, Markus Luster

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1. Introduction

Ethics approval has been granted to all investigating clinical centres of WP3 (see Table 1) by the respective ethics committees for an observational clinical study and recruitment of 100 patients across four centres has started. WP3 has set up the first multi-centre clinical study to establish the radiation-absorbed dose required for successful treatment and to measure absorbed doses to healthy organs for patients treated with radioiodine for thyroid cancer.

Table 1: Ethical approval dates for each centre participating in the WP3 prospective clinical study.

Investigating centre	Ethical approval obtained
UKW	9 th May 2019
UMR	14 th May 2019
IUCT-O	17 th Dec 2019
RMH/ICR	19 th March 2020

2. Patient recruitment numbers as of 18/09/2020

The midterm recruitment report was scheduled for the time point when 50% of the study population were expected to be recruited for this clinical study. While ethics approval was delayed in all centres which led to the late submission of D3.4 and Milestone 12, patient recruitment has exceeded expectations. Even though patient recruitment was stopped at all clinical centres during the COVID19 pandemic, more than 50% of patients have been recruited to date. As of 18/09/2020 a total of 69 patients had been recruited for the WP3 clinical study.

Figure 1 presents the quarterly recruitment numbers. The slower recruitment rate due to the COVID19 pandemic which stopped recruitment in centres from approximately March to June 2020 is clearly visible.

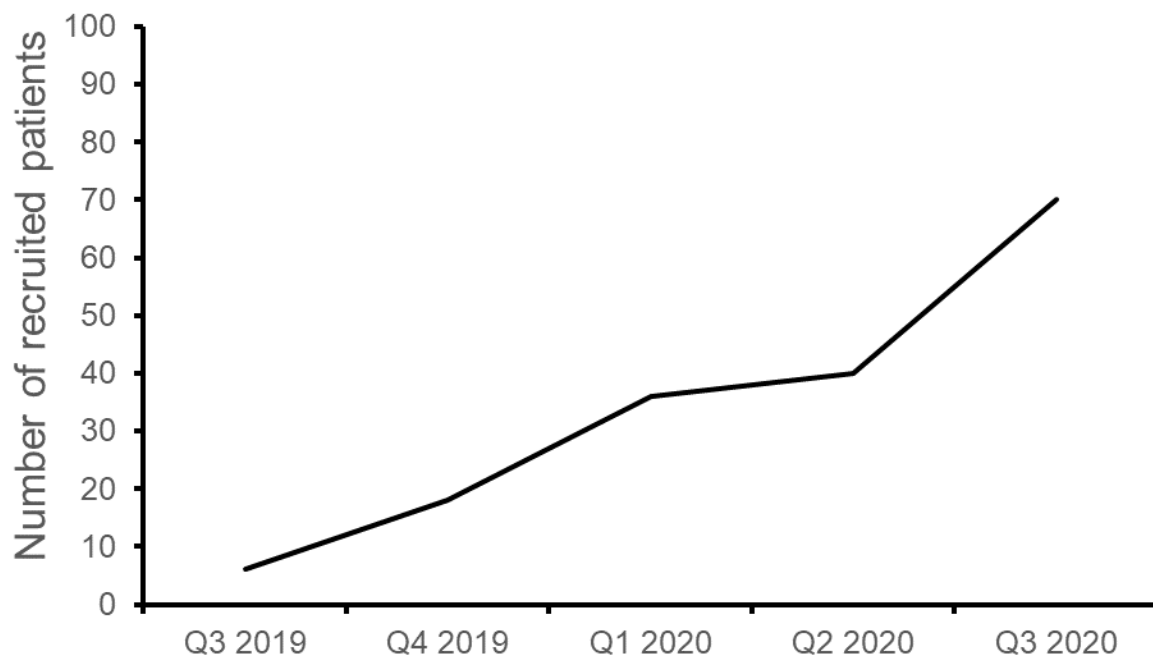


Figure 1: Quarterly recruitment number for the WP3 clinical study from Q3 2019 to present.

Table 2 shows the recruitment numbers for each of the centres as of 18/09/2020.

Table 2: Patient recruitment per centre

Investigating centre	Patients recruited as of 18/09/2020
UKW	15
UMR	35
IUCT-O	13
RMH/ICR	6

3. Future patient recruitment

Assuming similar recruitment rates as achieved pre- and post-Covid19 restrictions, the recruitment target of 100 patients is expected to be achieved around January/February 2021. A recruitment rate of ~ 10 patients per month across all clinical centres is expected.

With the number of Covid19 cases increasing across Europe there is a potential for further restrictions being imposed which could limit the ability of some or all of the WP3 centres to recruit patients for this prospective clinical study. Proposed risk mitigation measures are to shift recruitment across partners if this is the problem of only one centre.

4. Conclusion

More than 50% of the study population, 69/100 patients, have been recruited for the prospective observational study as part of WP3. It is expected that the recruitment target of 100 patients is met in early 2021.