Poster 21

Design of the non-interventional, prospective study CLADQoL (CLADribine Tablets – evaluation of Quality of Life)

Iris-Katharina Penner[1], Torsten Wagner[2], Anita Posevitz-Fejfár[2]

[1]COGITO Center for Applied Neurocognition and Neuropsychological Research, Düsseldorf, Germany; [2]Merck Serono GmbH, Darmstadt, Germany

INTRODUCTION

- Receiving marketing authorization in Germany on August 22nd, 2017, Cladribine tablets represent the first oral short-course treatment indicated for adult patients with relapsing multiple sclerosis (RMS)[1].
- Patients' health-related quality of life (HRQoL) has been shown to be an important patient reported outcome for overall benefit assessment.
- To date, no real-world data are available on QoL of RMS patients treated with Cladribine tablets.
- Furthermore, real-world longitudinal data on cognitive status as well as data on advantages and disadvantages of Cladribine tablets from a patient's perspective are lacking.

OBJECTIVES

- This study aims to investigate the quality of life of RMS patients initially treated with Cladribine tablets.
- The primary endpoint was defined as improvement of HRQoL after 24 months (MSQoL-54-assessed).
- Secondary endpoints include cognitive status, treatment satisfaction, relapse rate, fatigue, disability progression, employment status and maintenance of treatment effect between 2 and 4 years.
- Other objectives (exploratory) are Cladribine tablets administration related aspects, participation in a Patient Support Program (PSP) and correlation with treatment satisfaction and quality of life.

METHODS

Study Design

- Non-Interventional Study (NIS) in patients with relapsing multiple sclerosis (RMS) treated with Cladribine tablets (3,5 mg/kg body weight) (Figure 1 and 2).
- Participants of this NIS have the possibility to take part in PASS as a continuation for long term observation of safety aspects of Cladribine tablets

Population

- Recruited patients are first-time users of Cladribine tablets and received treatment according to the German SPC. A signed informed consent is required.
- Patient with per label contraindications are excluded.

Variables

- Demographic data, MS and medication history, disease course (relapse rate, disability, MRI) laboratory values and safety data
- Questionnaires: MSQoL (generic and total score), TSQM (total and subscores), SDMT and FSMC (total and subscores)
- Usage and service related experience, PSP participation and employment status

Data Sources

- Data will be collected by means of an eCRF; paper questionnaires will be filled out by the patient and then transferred into an eCRF by the study nurse.

Figure 1: Study design

- Start of study: Nov 2017
- End of recruitment: Mar 2020
- Documentation period per patient: 48 months
- Interim analyses I: after visit at 24 months for 30% of patients
- Interim analysis II: after visit at 24 months for all patients (Q4 2021)
- Final Report: June 2024

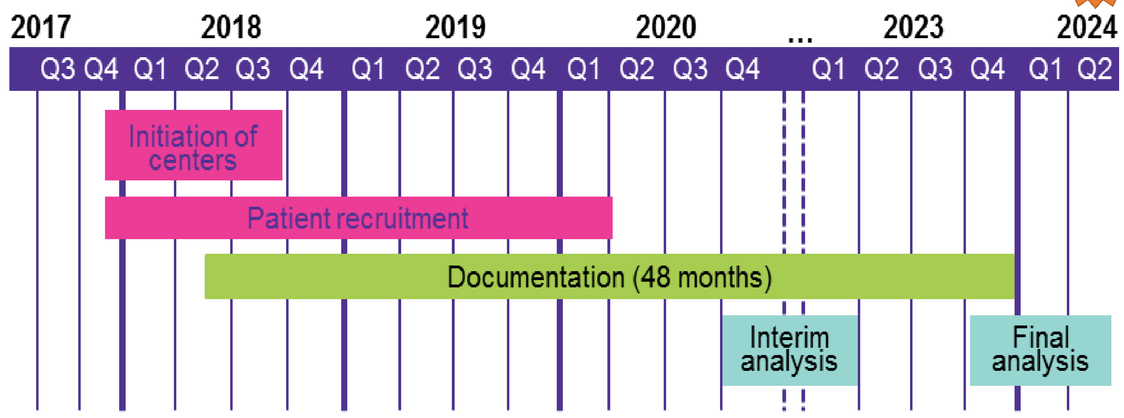
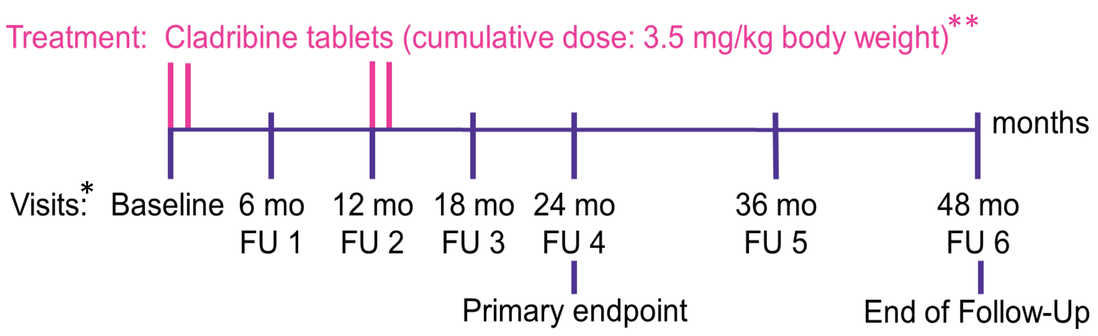


Figure 2: Study size, timeline and cladribine treatment

- Study size:
  - 385 patients with RMS who have been prescribed Cladribine tablets according to the German SPC.
  - 75 study centers in Germany and Austria
- Inclusion of 1st patient: March 8th, 2018



* Records produced at baseline and every 6 months (until 24 months) or on annual basis (until 48 months).; FU: Follow-Up;
** Cladribine tablets: 3.5 mg/kg body weight over 2 years, 1 treatment course (2 treatment weeks, beginning of the 1st and 2nd month of the respective treatment year. Each treatment week consists of 4 or 5 days on which a patient receives 10 mg or 20 mg (one or two tablets) as a single daily dose, depending on body weight.

Table 1: Visit plan

Assessment	Screening	Baseline	Documentation of visit (months)						Study termination (loss to FU, exclusion, IC withdrawal)
			6°	12*	18**	24**	36**	48**	
Demography	-	✓	-	-	-	-	-	-	-
Medical History	-	✓	-	-	-	-	-	-	-
Quality of life (MSQoL-54)	-	✓	-	✓	-	✓	✓	✓	✓
Cognition (SDMT)	-	✓	-	✓	-	✓	✓	✓	✓
Treatment Satisfaction (TSQM)	-	✓	✓	-	✓	-	-	-	✓
Fatigue (FSMC)	-	✓	-	✓	-	✓	✓	✓	✓
Employment status	-	✓	-	✓	-	✓	✓	✓	✓
PSP participation	-	✓	✓	✓	✓	✓	✓	✓	✓
Usage related questionnaire	-	-	✓	-	✓	-	-	-	✓
Service related questionnaire	-	-	✓	-	✓	-	-	-	✓
Reason for study termination	-	-	-	-	-	-	-	-	✓

Documented if recorded: EDSS score, 9-HPT score, T25-FW score, MRT (number of new lesions), relapse rate, laboratory values
FU: follow-up; IC: Informed Consent; PSP: Patient Support Program; ° Time slot: +/- 1 month; * Time slot: 6 months, according to specifications for treatment in the second treatment phase; ** Adjusted to documentation at visit 3 (12 months): approx. 6, 12, 24 and 36 months after first administration in the second treatment phase
Medical History: MS, malignancies, infections; History of therapy: DMD therapies, immunosuppressants; MS history: number of relapses, number of new MRT lesions (active T1 and new T2 lesions) within 12 months, degree of disability

CONCLUSION

This study investigates a prospective assessment and annual follow-up of health-related quality of life of RMS patients receiving Cladribine tablets. It will thereby provide essential real-world data for overall benefit assessment of cladribine treatment.

ACKNOWLEDGEMENTS

This trial was sponsored by Merck KGaA, Darmstadt, Germany. The authors would like to thank the patients, investigators, co-investigators, and study teams at each of the participating centers and at Merck KGaA, Darmstadt, Germany, and Merck Serono*, Darmstadt. Medical writing assistance was provided by med:unit GmbH and funded by Merck Serono*, Darmstadt, Germany.
*An affiliate of Merck KGaA, Darmstadt, Germany

REFERENCES

1. SmPC MAVENCLAD 10 mg tablets (May 2018)

DISCLOSURES

IKP has received honoraria for speaking at scientific meetings, serving at scientific advisory boards and consulting activities from Adamas Pharma, Almirall, Bayer Pharma, Biogen, Desitin, Genzyme, Merck Serono, Roche, Novartis and Teva. She has received research support from Merck Serono, Novartis, the German MS Society and Teva. TW and APF are employees of Merck Serono GmbH, Darmstadt, Germany.

Copies of this poster obtained through QR (Quick Response) code are for personal use only and may not be reproduced without written permission of the authors.

GET POSTER PDF

Presented at 26th Annual Meeting of the European Charcot Foundation; 15 – 17 November, 2018; Baveno, Italy.