Evaluating the Feasibility of Pandemic Forward, Telehealth Based Home Based Infusions for Ocrelizumab Users: Measuring Patient Experiences and Safety Outcomes

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Objective

- To evaluate the frequency of infusion-related reactions (IRRs) and patient-reported outcome (PROs) following administration of ocrelizumab (OCR) as a 2-hour home infusion

Background

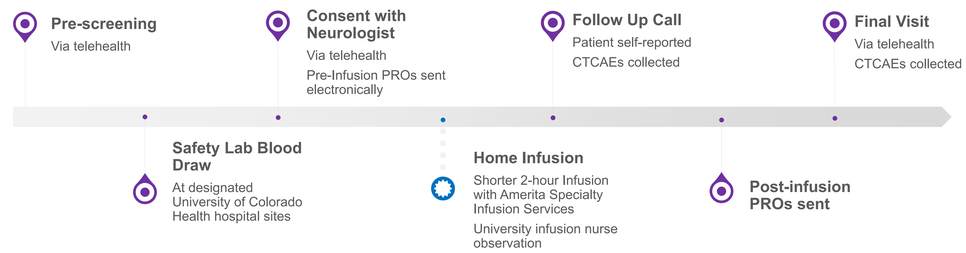
- OCR is a recombinant, humanized monoclonal antibody that targets CD20-expressing cells and is an approved disease-modifying therapy for multiple sclerosis (MS)[1]
- Site of care management (SOC) is a way for payers to determine where a patient can receive specialty drugs
- Home infusions have demonstrated similar health outcomes and number of adverse events (AEs) compared with hospital-based infusions[2], but a home infusion model of SOC for OCR using the short infusion protocol has yet to be evaluated
- During the SARS-CoV-2 pandemic, a home-based infusion delivery coupled with telehealth visits could help immunocompromised patients with MS maintain their social distancing strategies while continuing to remain cost effective for payers
- Home-based shorter infusions of OCR and telehealth visits could benefit both patients and payers by providing a safe, convenient and cost-effective method of infusion administration, especially during the SARS-CoV-2 pandemic

Methods

- 100 patients of the Rocky Mountain MS Center were selected that met the following criteria: ages 18-55, with relapsing or primary progressive MS, have completed first 600-mg dose of OCR; have neurologist-approved-therapy-monitoring labs; reside in area with 911 access; ability to complete PROs in English; and no ≥Grade 3 IRR in prior infusions
- Primary outcome: IRRs with common terminology criteria for adverse events (CTCAE) collected at the infusion visit, 24 hours post-infusion and 2 weeks post infusion via telehealth. Clopper-Pearson exact 95% confidence intervals.
- Secondary outcome: measure of patient experience with home infusion and factors that influence these experiences; patients were asked to compare their home infusion vs last OCR infusion (paired T-test (alpha=0.05)) using PROs measuring infusion experience, nurse responsiveness and confidence in receiving a home infusion.
- Home infusion provided by Amerita Specialty Infusion Services, trained by University of Colorado Health CTRC nurses*

Results

Figure 1. Study Design



Schedule of Events: screening, blood draw, informed consent with treating neurologist, home infusion, follow-up phone call, study close out virtual visit

Table 1. Current Enrollment

	N
	925
Number of eligible patients contacted	229
Final study consent signed	68
Completed infusions	56
Completed final study visit	51

Table 2. Patient Demographics and Clinical Characteristics

	Completed Group N=51
Patient Characteristics	
Age, mean (SD) [range], years	42.1 (8.4) [25.7-55.5]
PDDS, median (IQR)	1 (0, 1)
Female, n (%)	37 (72.6)
Race, n (%)	
White	46 (90.2)
Black	2 (3.9)
Asian	0 (0.0)
Native American	0 (0.0)
Other	3 (5.9)
Ethnicity, n (%)	
Hispanic	2 (3.9)
Non-Hispanic	49 (96.1)
MS Type, n (%)	
PPMS	3 (5.9)
RRMS	48 (94.1)
MS disease duration, mean (SD), years[a]	8.2 (6.1)
Years receiving ocrelizumab, mean (SD)	3.0 (1.4)

[a]n=50. PDDS, patient-determined disease steps

Figure 2. IRR Frequencies

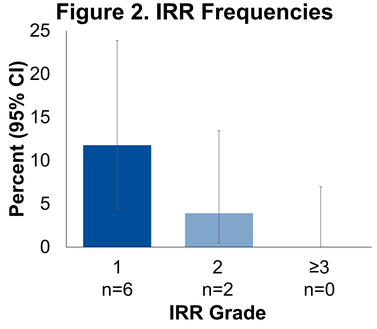
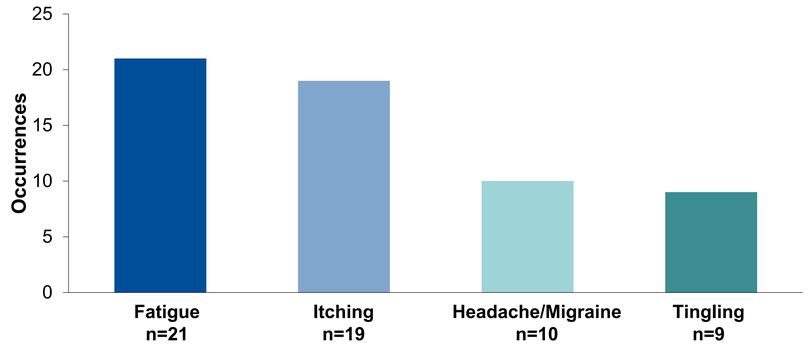


Table 3. IRR Frequencies

IRR Grade, n (%)	Completed Group N=51
Any IRR	8 (15.69%)
Grade 1 IRRs	6 (11.76%)
Grade 2 IRRs	2 (3.92%)
Grade 3 IRRs	0 (0.00)
Grade 4 IRRs	0 (0.00)
Grade 5 IRRs	0 (0.00)

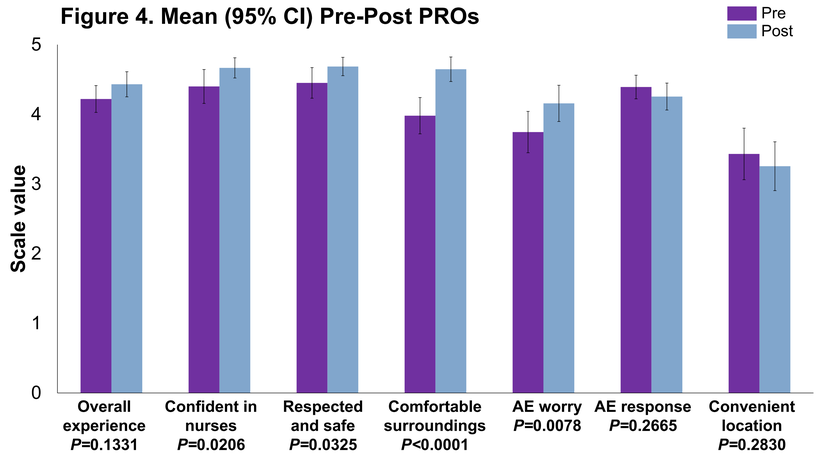
- 15.69% of infused patients (N=51) experienced an infusion related reaction

Figure 3. Most Common Self-Reported CTCAEs



- AEs were self-reported in 82.35% of patients.
- No SAEs were reported.

Figure 4. Mean (95% CI) Pre-Post PROs



- These PROs showed improvements pre vs post home infusion (range 1-5, higher is better)
- Patients reported a significant increase in confidence in nurses administering infusion (pre=4.40, post=4.67; *P*=0.02); feeling safe and respected during infusion (pre=4.45, post=4.69; *P*=0.03) and feeling comfortable in surroundings (pre=3.98; post=4.65; *P*<0.0001)
- Patient worries about AEs decreased (pre=3.75; post=4.16; *P*=0.008)

Conclusions

- IRRs and AEs occurred at an acceptable rate during home infusions
- Patients reported increased confidence and comfort during home infusions and decreased worry about AEs
- Interim analysis of patient reported outcomes from rapid ocrelizumab infusions administered at home is promising

Disclosures: Drs Vollmer, Nair and Alvarez have a financial interest in Genentech, Inc., the study sponsor and manufacturer of ocrelizumab.

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1. OCREVUS (ocrelizumab injection, USP) U.S. Package Insert. Genentech.
2. Polinski JM, Kowal MK, Gagnon M, et al. Home infusion: Safe, clinically effective, patient preferred, and cost saving. *Healthcare* 2017; 5: 68–80.