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The Patient Perspective in Systemic Lupus Erythematosus (SLE) Clinical Trials: A Focus Group Study

A variety of novel experimental treatments have emerged for SLE including 'Chimeric' Antigen Receptor (CAR) T-Cell therapies. However, clinical trials in SLE are often impeded by recruitment and retention challenges. The objective of our focus group study was to identify barriers and facilitators perceived by people with SLE regarding participation in clinical trials for novel/advanced therapies.

Adults followed in our SLE research cohort were invited to participate in 1-hour virtual focus group discussions concerning their perspectives on clinical trials for novel/advanced SLE therapies. Sessions were run by a trained moderator and co-moderator who facilitated discussion using a set of standardized questions. Sessions were recorded and transcripts were generated and analyzed. An inductive thematic analysis approach was used to code the qualitative data and generate themes/sub-themes.

Nineteen patients participated in four focus groups (two in English, two in French). The mean age (range) was 50.0 (21-77) years, most (89.5%) participants were female, and 78.9% (15/19) were White, with the rest being Black, Asian, and Hispanic. Most (78.9%, 15/19) felt their disease was currently stable.

Six main themes emerged: the first two related to barriers and the remaining four related to facilitators to participation in trials of novel/advanced drug therapies. The first theme identified logistical constraints such as employment and travel making time commitment difficult. The second theme demonstrated patients' risk aversion, including subthemes of fear of SLE flare or drug side effects and hesitancy regarding treatments in early trial phases. The remaining themes concerned facilitators or drivers of trial participation. One facilitator was having clear, detailed clinical trial information. Disease instability despite standard therapies was another driver of interest in clinical trial participation. Desire to support the lupus community was also a driving factor. The final theme identified that access to mental health counsellors, peer support, and close medical follow-up (offered in clinical trials) were strong facilitators of participation.

We identified potential barriers and facilitators/driving factors regarding participation in SLE clinical trials of novel/advanced agents like CART therapies. Key barriers identified include logistical constraints such as time commitment, employment and travel, and risk aversion. Facilitating factors include clear and comprehensive information, perceived benefit to the lupus community (especially regarding new treatments for resistant SLE), and the availability of peer groups, mental support and attentive healthcare in a trial. This can help optimize SLE clinical trial design and execution, in the era of novel/advanced agents like CART therapies.