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Patient-reported experiences and quality of life outcomes in the TB-PRACTECAL clinical trial: PRACTECAL-PRO

***Beverley Stringer**[1], Karen Lowton[2], Martina Cusinato[3], Katherine Fielding[3], Irina Liverko[4], Ronelle Moodliar[5], Tigay Zinaida Nikolaevna[6], Varvara Solodovnikova[7], Bern-Thomas Nyang'wa[3,8]

[1]Médecins Sans Frontières (MSF), London, UK; [2]University of Sussex, Brighton, UK; [3]London School of Hygiene and Tropical Medicine, London, UK; [4]Republican Specialized Scientific Research Medical Centre of Phthisiology and Pulmonology, Tashkent, Uzbekistan; [5]THINK (TB & HIV Investigative Network), Durban, South Africa; [6]Nukus TB Hospital and Out-Patient Department, Nukus, Uzbekistan; [7]Minsk Republican Scientific and Practical Centre of Pulmonology and Tuberculosis, Minsk, Belarus; [8]MSF, Amsterdam, The Netherlands

*beverley.stringer@london.msf.org

Introduction

The TB-PRACTECAL study trialed a shorter, more tolerable regimen of oral drugs than standard of care (SoC) – which can last for up to 20 months and involve both injectables and up to 20 tablets a day. In this sub-study, PRACTECAL-PRO, we measured and explored trial participant quality of life, experiences, and perspectives on treatment, to understand outcomes more fully. Both studies were conducted in Uzbekistan, South Africa, and Belarus.

Methods

We conducted a mixed-methods evaluation using quality of life (QoL) surveys and in-depth interviews. Participants in investigational and SoC arms completed the Short Form 12 (SF-12) and St George's Respiratory Questionnaire (SGRQ) at four timepoints (baseline, 12, 24, and 48 weeks). Healthy age- and sex-matched volunteers were surveyed at a single timepoint to establish locally relevant controls. Participants from investigational arms were purposively sampled for in-depth interviews to describe qualitatively patient satisfaction and experience with the investigational arm trial, including factors enabling toleration or rejection of a novel treatment by patients.

Ethics

This study was approved by the MSF Ethics Review Board and by the ethics review committees of the Ministry of Health of the Republic of Uzbekistan; the Republican Scientific and Practical Centre for Pulmonology and Tuberculosis, Belarus; the regulatory authority of the Ministry of Health of the Republic of Belarus and Pharma Ethics Independent Ethics Committee, South Africa.

Results

Overall, of 137 trial participants 28.5% (39) and 71.5% (98) were randomised to the SoC arm and one of three investigational arms, respectively. Statistically significant univariate scores by arm were observed at week 48 for SGRQ Impact domain (median -3.8, 95% confidence interval (CI), -5.7 to 0.0) and at week 24 for SF-12 physical component score (median 3.1, 95%CI 0.2 to 6.7). Longitudinal analysis showed that the proportional reduction in SGRQ scores per month was higher in the investigational group compared to the SoC for all domains and the total score. For both the SGRQ and SF-12, baseline scores indicated worse quality of life for the trial participant group (that is, investigational arms and SoC together) than for the healthy control group. Qualitative analysis showed early treatment satisfaction was a useful predictor of better adherence. Treatment acceptability was linked to participants' support networks and their experience of counselling and clinical advice. Tolerability of the regimen helped reassure patients and household members on efficacy and value of the treatment. Participants reported that early improvement helped them return to productive lives sooner, with the potential to address social determinants with financial protection schemes for a shorter investment period. Patient perspectives around residual burden of disease can help inform clinicians about ongoing care.

Conclusion

All PRACTECAL-PRO participants reported worse generic and disease-specific QoL at baseline, compared to an age- and sex-matched healthy control group. Participants taking a novel shortened oral regimens demonstrated both a quicker improvement in their respiratory disease-specific QoL over 48 weeks than those receiving SoC, and an improvement that exceeded the SGRQ's minimum clinically important difference. In-depth interviews give insights suggesting investment toward patient-sensitive and socially responsive treatment and care. For interviewees, the supportive care experienced was as important as their satisfaction and tolerability of the novel drug regimen. Patient perspectives are an essential component of assessing clinical trial outcomes.

Conflicts of interest

None declared.