

ギルド名  
だぶいめかり

## —ギルドマスター—

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1. **What is the primary purpose of the study?** The study aims to evaluate the effectiveness of a new treatment for hypertension in a diverse population.

2. **What are the inclusion and exclusion criteria for the study?** Inclusion criteria: patients aged 18-65 with systolic blood pressure ≥ 140 mmHg. Exclusion criteria: patients with contraindications to the study drug, pregnant or lactating women, and those with a history of severe adverse reactions to the drug.

3. **What are the study endpoints and how will they be measured?** Primary endpoint: change in systolic blood pressure at 12 weeks. Secondary endpoints: change in diastolic blood pressure, change in quality of life scores, and adverse event rates.

4. **What is the study design and duration?** The study is a randomized, double-blind, placebo-controlled trial. Duration: 12 weeks.

5. **What is the sample size and how will it be recruited?** Sample size: 300 patients. Recruitment: through physician referrals and community advertisements.

6. **What are the safety and adverse event monitoring procedures?** Adverse events will be monitored throughout the study. A safety committee will review all adverse events and determine if they are related to the study drug.

7. **What is the statistical analysis plan?** The primary analysis will be a comparison of the change in systolic blood pressure between the treatment and placebo groups. Secondary analyses will include comparisons of change in diastolic blood pressure, quality of life scores, and adverse event rates.

8. **What is the timeline for the study?** The study is currently in the planning phase and is expected to begin enrollment in early 2024.

9. **What is the budget for the study?** The budget for the study is approximately \$1.5 million.

10. **What is the funding source for the study?** The study is funded by a pharmaceutical company and the National Institutes of Health.