kite-ai Your Decision Partner

Exploring the Impact of Study drug on PCOS

Insights from Our Recent Phase III Clinical Study

Introduction

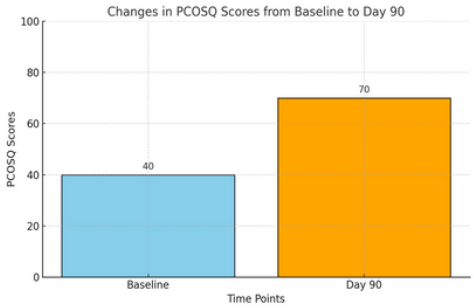
Polycystic Ovary Syndrome (PCOS) is a common endocrine disorder affecting women of reproductive age, characterized by irregular menstrual cycles, hyperandrogenism, and polycystic ovaries. Symptoms include weight gain, acne, hirsutism, and infertility, along with metabolic disturbances like insulin resistance and dyslipidemia.

Purpose of study

To evaluate the efficacy and safety of a Study drug in improving clinical and biological parameters in women with PCOS. The study aimed to determine if the Study drug could alleviate symptoms and enhance the overall quality of life by improving gut health and hormonal balance.

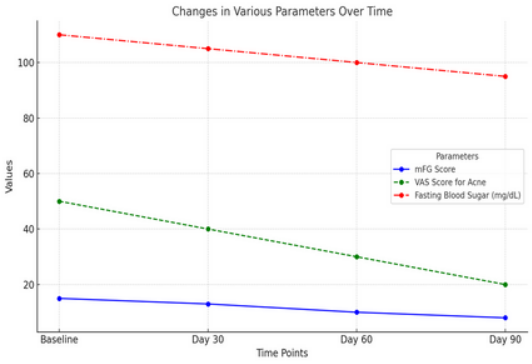
Primary Outcome Measure

Change in PCOSQ Score: The study measured the change in the Polycystic Ovary Syndrome Questionnaire (PCOSQ) score from baseline to Day 90 to assess the effectiveness of the Study drug in improving the quality of life for women with PCOS.



⋆Dummy data used, and image is for representation purpose only.
The actual data and visualization remain confidential as a part of the CDA and DECP.

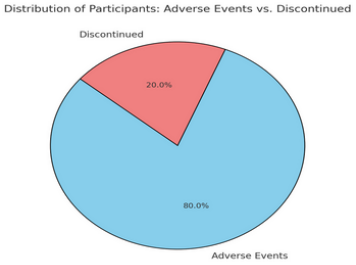
Secondary Outcome Measures



- Change in PCOSQ score at intermediate time points.
- Change in scores assessing physical symptoms like hair growth and acne.
- Change in blood sugar levels and HbA1c.
- Change in hormone levels, including FSH, LH, estradiol, and testosterone.
- Change in lipid profile parameters, such as triglycerides, total cholesterol, LDL, and HDL.

Safety Endpoints

Number of participants who experienced adverse events and those who discontinued the study drug.



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Conclusion

The primary outcome measure showed a significant improvement in the PCOSQ score from baseline to Day 90, indicating the effectiveness of the Study drug in enhancing the quality of life for women with PCOS.

Secondary outcome measures demonstrated improvements in various clinical and biological parameters, including hormonal balance, insulin sensitivity, and lipid profiles.

Safety endpoints were monitored, with a record of participants who experienced adverse events and those who discontinued the study drug.

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