CLINICAL TRIAL RESULTS

Template:
1. Crisaborole Ointment 2% Skin Biomarker Biopsy Study in Atopic Dermatitis | Pfizer (2020)
2. https://clinicaltrials.gov/submit-studies/prs-help/plain-language-guide-write-brief-summary

This is a summary of the results from a single clinical study.

Sponsor:	ABC Company, 2025 Rockabilly Park Dr, Nowhere, MD 12345
Medicine(s) Studied:	Tapencarium (RZL-012 high dose and low dose) and placebo
Protocol Number:	RZL-012-SMF-P2bUS-001
Dates of Trial:	15 June 2021 to 31 May 2022
Title of this Trial:	Efficacy and Safety of Tapencarium (RZL-012) in Submental Fat Reduction [A Double Blind, Randomized, Three-arm, Placebo-Controlled Phase 2b Study to Evaluate the Efficacy and Safety of Tapencarium (RZL-012) in Subjects Seeking Submental Fat Reduction]
Date of this Report:	2023-06-26

- Thank You -

ABC Company, the Sponsor, would like to thank you for your participation in this clinical trial and provide you with a summary of the results, presenting everyone who participated. If you have any questions, please contact the doctor or staff at your study site.

Why was this study done?

Accumulation of submental fat will negatively affect people in all age groups because of the aesthetic concern. It may lower their self-esteem and social activity. According to an online survey, 70% of the participants were displeased with their excessive fat under the chin or neck.

RZL-012 is a newly created chemical compound available for the treatment of submental fat in a single treatment. RZL-012 is injected beneath the skin and acts to destroy fat cells at the site of injection. After the injection, a temporary inflammation occurs, leading to a healing process. Moreover, an excess buildup of collagen replaces the previous fat tissue. Based on previous studies, RZL-012 has demonstrated efficacy in long-term reduction of the total amount of the layer of fat directly beneath the skin. Its potential risks and adverse reactions have been considered acceptable.

The goal of this clinical trial is to learn if drug RZL-012 works to reduce submental fat in both male and female adult participants aged from 18 to 65, with excess submental fat. It will also learn about the safety of drug RZL-012.

The main questions it aims to answer are:

- Does drug RZL-012 reduce the submental fat of the participants?
- What medical problems do participants have when taking drug RZL-012?

Researchers compared drug RZL-012 (high dose) and RZL-012 (low dose) to a placebo (a look-alike substance that contains no drug) to see if drug RZL-012 works to reduce submental fat.

Participants:

- Received a single injection of RZL-012 (high dose), RZL-012 (low dose), or a placebo in the submental area
- Be monitored for 84 days

What happened during the study?

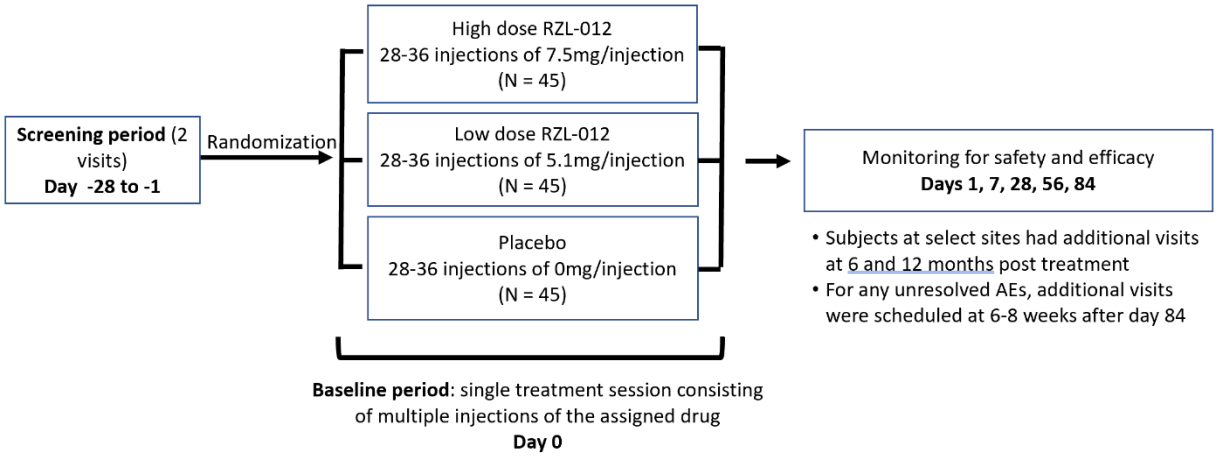
This was a phase 2B double-blind, randomized, dose-ranging, placebo-controlled study. Male and female participants aged 18 to 65, with excess submental fat, were included in the study.

Researchers randomized each participant to either active treatment (high- or low-dose RZL-012) or placebo at a ratio of 1:1:1 per group as follows:

· Low dose: 28 to 36 injections of 5.1 mg/injection point, resulting in an average dose of 166 mg/participant (53 participants)

· High dose: 28 to 36 injections of 7.5 mg/injection point, resulting in an average dose of 244 mg/participant (50 participants)

· Placebo: 28 to 36 injections of inactive ingredients, resulting in a dose of 0 mg/participant (48 participants)



A total of 151 eligible and consenting participants were enrolled in the study. The majority of participants were female (80.1%), white (74.2%), with an average age in all groups between 41.6 and 44.6 years (range, 20 to 65).

Table 1. Demographic Data

	RZL-012 high dose	RZL-012 low dose	Placebo
	n (%)	n (%)	n (%)
Gender			
Male	8 (16)	8 (15.1)	14 (29.2)
Female	42 (84)	45 (84.9)	34 (70.8)
Country			
USA	50 (100)	53 (100)	48 (100)

What were the results of the study?

The proportion of participants who had a 1-grade or 2-grade improvement in C-CAT and/or S-CAT on Day 84 vs baseline (starting point) was significantly higher in the high-dose RZL-012 group vs the placebo group (P < .002). The relative percentage reduction in MRI-measured submental fat volume (Day 84 vs screening) was significantly greater in the high-dose RZL-012 group vs the low-dose RZL-012 or the placebo group (P < .0001). A single administration of RZL-012 into submental fat resulted in significant improvement in submental appearance as assessed by clinicians, participants, and MRI.

Local injection site reactions were the most common adverse events (AEs). However, from a safety perspective, there were no serious AEs and no clinically significant changes in vital signs or laboratory tests throughout the study.

Table 2. Incidence of Major 4 Adverse Reactions Reported

		Placebo (n=48)		RZL-012 low dose (34 mg/mL) (n=53)		RZL-012 high dose (50 mg/mL) (n=50)	
		n	%	n	%	n	%
Digestive issues	Difficulty swallowing	2	4.2	21	39.6	15	30.0
Digestive issues and injection site conditions	Injection site bruising	20	41.7	17	32.1	18	36.0
	Injection site swelling	16	33.3	18	34.0	17	34.0
	Injection site edema	27	56.3	27	50.9	21	42.0
	Injection site pain	23	47.9	31	58.5	34	68.0

Limitations of the study included the inclusion of participants with BMIs (Body Mass Index) between 22 and 40 only, and a lack of long-term follow-up.

Where can I learn more about this study?

If you have questions about the results of your study, please speak with the doctor or staff at your site. The full scientific report of this study is available online at:

https://clinicaltrials.gov/ Use the study identifier NCT04867434

Again, thank you for volunteering.
We do research to try to find the best ways to help participants, and you helped us to do that.