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Released: 07/02/2026
Valid until: 07/02/2026
Time needed to complete: 47m

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Comparing Trial Designs & Outcomes Across IGF-1R Therapies

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Episode 7

Dr. Cockerham:
Hi, I'm Dr. Kimberly Cockerham. Here with me today is Dr. Andrea Kossler.

In another episode, we discussed the different IGF-1 inhibitors in thyroid eye disease. Let's dive a little deeper.

What have we learned more recently? Let's take a look at the current data on these agents, both intravenously and subcutaneously. Andrea, what can you tell us?

Dr. Kossler:
Well, it's been an exciting time in thyroid eye disease, from the prior phase 2 and 3 studies with teprotumumab to new clinical data that's being released. There's been a lot of excitement with drug development, so let's get into the studies.

The OPTIC study is the phase 3 study for teprotumumab, where they looked at patients that had moderate to severe thyroid eye disease, and this was a randomized, double-blinded, placebo-controlled trial, and what they found was that patients that were treated with teprotumumab had significant improvements in proptosis, diplopia response, and overall response, and even improvement in CAS score to 0 or 1 compared to placebo.

And then these patients that were in the OPTIC study that went into the open-label study, we found that patients with longer-duration disease had similar proptosis response rates to patients that had more acute disease, on average 12 months in the OPTIC-X study and 6 months in the OPTIC study. So, this was the first time that we realized that maybe disease duration doesn't matter as much as we first thought that it did. Maybe other factors matter more.

Then there was a phase 4 study that looked at patients that had low CAS and chronic moderate to severe thyroid eye disease. And this study found that when compared to placebo, teprotumumab-treated patients had about a 1.5-mm improvement in proptosis overall, and about 62% of patients had a proptosis response rate, and that was compared to about 25% in the placebo group.

And so, this phase 4 study showed significant improvement in proptosis response compared to placebo, but there wasn't a significant improvement in diplopia response or in quality of life improvement.

Now let's switch gears to the new IGF-1 inhibitor, veligrotug, which has been studied in the THRIVE trial for patients with active thyroid eye disease of 15 months' duration or less. And what this study showed us was that patients treated with teprotumumab had significant improvements in proptosis response, diplopia response, and in their CAS improvement to 0 to 1 when compared to placebo. And all of

these were clinically significant, which was exciting to see a new IV IGF-1 inhibitor that could potentially be a treatment option for our patients.

They then did a study looking at patients with chronic disease, so disease of 15 months or more, and similarly they found a significant improvement in proptosis response, diplopia response, and CAS improvement to 0 to 1. But you'll notice that the numbers are a little less, so about 56% compared to 8%, 56% improvement in diplopia, 54% improvement in that CAS score, but all were statistically significant.

What's also really exciting are the new REVEAL studies, which look at a subcutaneous formulation of IGF-1 inhibition with a drug called elegrobart. And so, the REVEAL-1 study is a phase 3, randomized controlled, double-blinded study where they looked at 3 different arms: placebo, patients that received subcutaneous injections every 4 weeks, and then another group that had every 8 weeks. So, these patients had active disease with a disease onset of within 15 months.

And what they found was that patients had a significant improvement in their proptosis response and their diplopia response rates, and even in diplopia resolution in the patients that received drug every 4 weeks compared to placebo, and also a significant improvement in proptosis response and overall response in patients that were treated every 8 weeks.

There was also the REVEAL-2 study. And these results were just recently released, where patients that were treated for chronic thyroid eye disease, so they had disease for over 15 months and any CAS score. When they were treated with subcutaneous IGF-1 inhibition, the study found significant improvements in proptosis response, in overall response, and even in diplopia response.

So, really exciting results in IV treatments, and even in subcutaneous treatments, so new drugs may become available with these results. So, really, an exciting time overall.

Dr. Cockerham:
Thank you so much, Dr. Kossler, for covering so much information in such a short period of time. I think it's amazing that we have now 2 potential intravenous products, and the subcutaneous data is now back with ELE [elegrobart], and we look forward to the subcutaneous data from the teprotumumab, and just it's amazing the evolution of the treatment for thyroid eye disease.

And thank you for listening. And thank you for being interested in thyroid eye disease, everyone who's listening. Thanks.

Dr. Kossler:
Bye, bye.

Announcer:
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