What is CAR T-cell therapy?

- CAR T-cells are a type of white blood cell that are an essential part of the immune system.
- ‘CAR’ stands for Chimeric Antigen Receptor.
- They are modified to engineer receptors on the surface of T-cells to recognize specific antigens on the surface of cancer cells.

What have we learned from the ELARA clinical trial?

- The main question asked in this trial (primary outcome measure) was how many patients showed no evidence of disease on scans or tests at any point during follow-up.
- There were two high-risk subgroups in which tisagenlecleucel was less effective than in corresponding lower-risk subgroups.
- Tisagenlecleucel maintained its effectiveness in most subgroups of patients who were considered to be at high risk for relapse or in second or subsequent relapse.
- The safety and effectiveness of tisagenlecleucel were monitored and assessed every 3 months after initial treatment.

Why is the ELARA clinical trial important?

- It is the first clinical trial to focus on patients with high-risk follicular lymphoma.
- It provides insights into the effectiveness and safety of tisagenlecleucel in high-risk subgroups.
- It helps to identify patients who may benefit from CAR T-cell therapy.

What is tisagenlecleucel?

- Tisagenlecleucel is a CAR T-cell therapy – a treatment using specially modified T-cells to target and destroy cancer cells.
- It is manufactured for each individual patient by using their own T-cells.

How is tisagenlecleucel manufactured?

- The patient’s own T-cells are collected and taken to a laboratory.
- The T-cells are then modified to express CAR receptors that target specific antigens on the surface of cancer cells.
- The modified T-cells are then expanded in number in the laboratory.
- The expanded T-cells are cryopreserved and then administered back to the patient.

What is the ELARA trial?

- The ELARA trial is a multinational, open-label, phase 2 clinical trial aimed at investigating the effectiveness and safety of tisagenlecleucel in patients with high-risk follicular lymphoma.
- It is being conducted in several countries, including the USA, UK, France, Spain, and Japan.

Where can I learn more?

- For more information on CAR T-cell therapy and tisagenlecleucel, visit the Novartis website or contact the Novartis medical information line.

Acknowledgments

- Medical writing assistance was provided by Isabelle Blomfield PhD, of Seques (an AMICULUM agency), which was funded by Novartis Pharmaceuticals Corporation.

References

- https://clinicaltrials.gov/ct2/show/NCT03568461

For patients who had a complete response, overall survival was 55% (95% CI 49%–61%) at the 2021 ASH Annual Meeting. Disk images that show a tumor shrunk in the first 8 weeks of treatment. Percentages represent the overlap of patients in each subgroup. The safety and effectiveness of tisagenlecleucel were monitored and assessed every 3 months after initial treatment.

What is a complete response?

- No evidence of disease on scans or tests.
- This is designed to lower the LDH.
- This is designed to lower the C-reactive protein, a protein made by the liver that is associated with inflammation.

CountrYs

- USA
- UK
- France
- Spain
- Japan
- Australia
- Germany
- NETHERLANDS

Subgroups

- FL, who had at least two previous immunochemotherapy treatments or a stem cell transplant, were able to participate in the trial.