Transcript: DANFLU-1 Results

**Dr. Tor Biering-Sørensen:**  I'm going to tell you about the DANFLU-1 trial which we presented here in Barcelona at ESC 2022.

The DANFLU-1 trial is a pragmatic feasibility trial testing whether it is feasible to randomize Danish citizens to two different types of vaccines within the Danish nationwide vaccine strategy. The purpose was to test the feasibility. So the outcomes that we also reported has to be thought of as hypothesis-generating.

We randomized Danish citizens between 65 to 79 to either a high-dose flu vaccine or standard-dose flu vaccine. We found that it is indeed possible to randomize the Danish citizens within the Danish flu vaccination strategy to these two different vaccines, and we manage to randomize close to 12 and a half thousand participants.

The reason why we want to conduct this trial is that we know that the high-dose flu vaccine protects 25% better against a positive flu test than the standard-dose, however, we don't know whether the high-dose flu vaccine protects against hospitalizations.

So conducting such a large outcome trial we would need to randomize close to 200,000 participants. However, before that trial can be conducted, we wanted to do this feasibility trial to test whether it is possible to conduct a trial within this strategy and with the sample size that I just mentioned. Besides testing the feasibility, we also, as mentioned, looked at explanatory outcomes.

We found that participants randomized to the high-dose flu vaccine had a 65% lower risk of being hospitalized for pneumonia or the flu. Furthermore, we saw that patients randomized to the high-dose had half the risk of dying compared to participants randomized to the standard-dose one.

Of course, these outcomes are only hypothesis-generating because the trial wasn't powered to assist these outcomes but was only a feasibility trial. So the next step is to conduct the sufficiently power trial to assist whether a high-dose flu vaccines protects more or better against hospitalizations for flu or pneumonia and also for cardiovascular outcomes in a fully powered randomized trial which can be conducted within this system.

But another point that we could, we took away from conducting this trial, is that it's possible within the nationwide Danish registries to conduct large-scale pragmatic outcome trials which now gives us the opportunity to conduct trials within several different aspects using these systems.

So thank you very much for listening.