



Dear contributors, colleagues and co-workers,

Today I have the pleasure to share with you the results from the second safety analysis, which took place on May 18, 2021. The safety committee received data on 2360 patients: 1483 from Sweden, 727 from Denmark, 43 from Greece, 29 from Italy and 78 from Germany. Keep in mind that Sweden had a head start of at least two years, and that the last two countries on the list only enrol mastectomy patients. The safety committee was satisfied with enrolment despite the pandemic (please see figures on the next page). Only Denmark actually *increased* accrual during 2020 while all other countries noted a slight decrease in enrolment rates.

Overall, there were 56 deaths, 23 of which were due to breast cancer. There was no significant difference between the two groups.

In conclusion, the safety committee saw no reason to discontinue the trial.

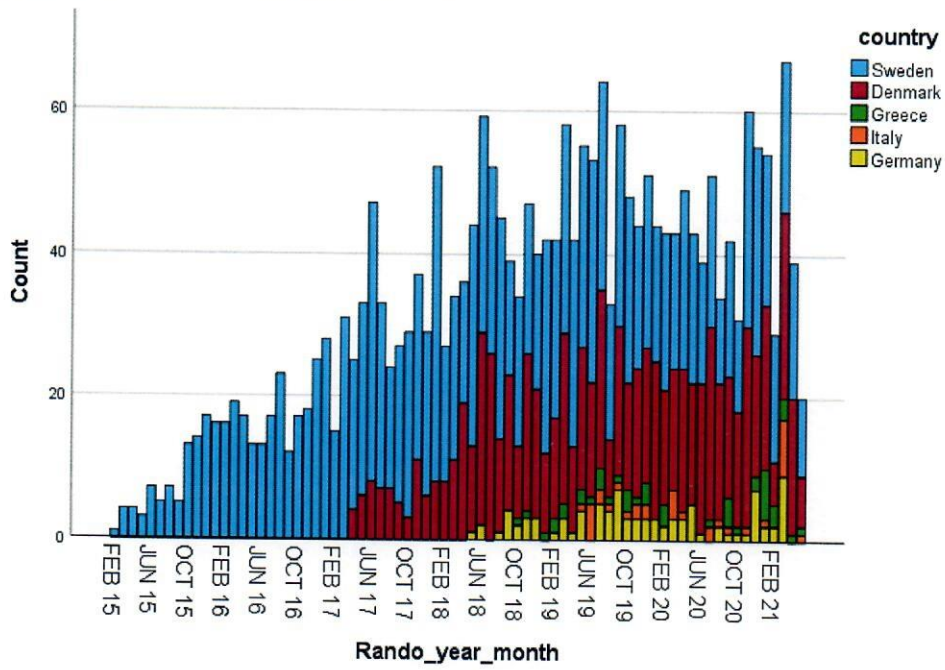
Until May 17, the number of total randomisations was 2486. In accordance with previous discussions, the Swedish steering board suggest that the trial should be closed by December 31, 2021. We should by then have recruited about 2800-2900 patients together, and with 2-3 years of additional follow-up, statistical power is expected to be reached.

I present to you the current figures and graphs on the following pages.

Now I wish you all a relaxing summer, stay healthy and hopefully enjoy some well-deserved holidays!

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1. Number of randomisations per month



2. Cumulative number of randomisations since start of trial

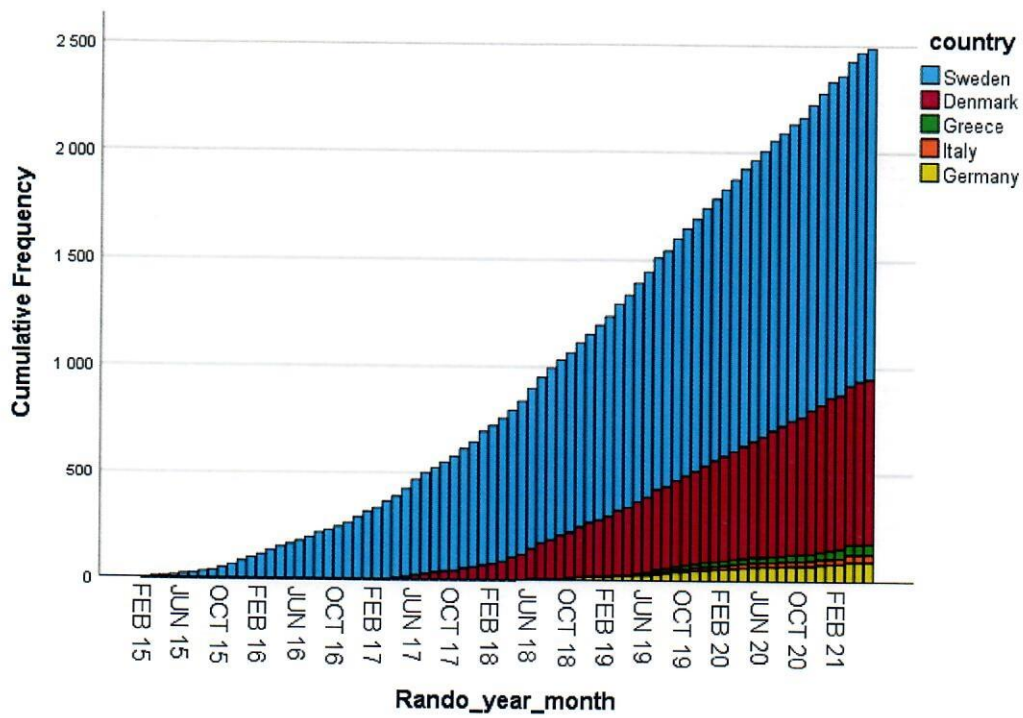


Table: Number of site-specific randomisations as of May 17, 2021

Please observe that this table only shows those sites that have generated randomisations as of 2021MAY17. For a list of all initiated sites, please see the trial homepage.

Site	Country	Initiation visit	First patient in	Number of randomisations
Karolinska	Sweden	2015-01-30	2015-02-27	118
Västerås	Sweden	2015-03-02	2015-04-14	57
S:t Göran	Sweden	2015-03-05	2016-06-07	184
Akademiska Uppsala	Sweden	2015-03-12	2016-02-14	48
Södersjukhuset	Sweden	2015-03-18	2015-11-24	144
Örebro	Sweden	2015-03-25	2015-10-01	54
Sahlgrenska	Sweden	2015-04-23	2015-06-10	108
Lund/Malmö	Sweden	2015-05-13	2015-10-13	118
Helsingborg	Sweden	2015-05-20	2015-07-23	57
Linköping	Sweden	2015-05-27	2016-11-03	100
Karlstad	Sweden	2015-05-28	2015-12-14	41
Lidköping/Skövde	Sweden	2015-06-04	2015-10-22	84
Uddevalla	Sweden	2015-06-04	2015-09-21	24
Kalmar	Sweden	2015-09-02	2016-03-03	21
Västervik	Sweden	2015-09-02	2016-02-18	32
Karlskrona	Sweden	2015-09-03	2015-12-14	8
Gävle	Sweden	2015-09-10	2015-12-30	47
Sundsvall	Sweden	2015-10-15	2015-10-29	65
Umeå	Sweden	2015-11-19	2016-02-10	62
Halmstad/Varberg	Sweden	2015-12-10	2016-02-17	30
Växjö	Sweden	2016-01-14	2016-03-23	40
Aarhus	Denmark	2016-11-28	2017-04-25	125
Randers	Denmark	2017-09-14	2017-11-07	18
Köpenhamn Rigshospitalet/Herlev	Denmark	2016-12-19	2017-04-20	256
Jönköping	Sweden	2017-01-20	2017-11-13	42
Kristianstad	Sweden	2017-03-20	2017-05-17	47
Borås	Sweden	2017-02-20	2018-09-14	9
Aabenraa	Denmark	2017-10-12	2017-12-13	74
Odense	Denmark	2017-11-22	2018-02-16	46
Esbjerg	Denmark	2017-12-12	2018-03-05	15
Viborg	Denmark	2017-11-03	2018-03-16	90
Aalborg	Denmark	2017-10-10	2018-02-07	90
Bad Langensalza	Germany	2018-04-04	2018-05-23	5
Rostock	Germany	2018-03-12	2018-06-07	14
Berlin Spandau	Germany	2018-04-19	2018-09-07	4
Laiko 1, Athens	Greece	2018-06-28	2018-10-12	16

Vejle	Danmark	2018-03-19	2018-11-07	57
Esslingen	Germany	2018-02-16	2018-10-26	2
Klinikum Kassel	Germany	2018-06-12	2018-11-22	1
Heraklion, Crete	Greece	2019-02-19	2019-03-07	9
Athens Euroclinic	Greece	2019-12-11	2019-02-12	12
Dresden	Germany	2018-05-02	2019-03-01	6
Hanau	Germany	2018-05-18	2019-02-12	11
Karlsruhe	Germany	2018-07-11	2018-12-18	1
Villingen-Schwenningen	Germany	2018-09-10	2018-12-28	1
Mittelbaden	Germany	2018-08-16	2019-03-13	3
Laiko 2, Athens	Greece	2018-11-07	2019-05-29	4
San Raffaele Milano	Italy	2018-02-01	2019-05-21	6
IEO Milano	Italy	2019-05-06	2019-06-06	25
Unna	Germany	2018-03-01	2019-05-28	6
Ebersberg	Germany	2018-04-10	2019-04-06	2
Stendal	Germany	2018-04-25	2019-05-14	1
Wiesbaden St. Josef	Germany	2018-06-14	2019-05-03	1
Worms	Germany	2018-08-28	2019-05-02	2
Potsdam	Germany	2019-06-18	2019-07-01	5
Tübingen	Germany	2019-09-04	2019-09-24	8
Böblingen	Germany	2018-07-10	2019-11-07	5
Wiesbaden Asklepios	Germany	2019-11-27	2020-01-28	5
Dresden St. Joseph	Germany	2019-10-08	2020-05-18	1
Bochum	Germany	2018-02-07	2020-05-05	4
Helena Venizelou	Greece	2020-07-30	2020-09-18	3
Brescia	Italy	2020-01-20	2020-11-23	4
Schkeuditz	Germany	2018-07-06	2020-12-11	2
Bietigheim	Germany	2020-09-11	2020-12-16	2
Attikon	Greece	2020-06-12	2021-01-22	4
Total				2486

Figure: Accumulated site-specific inclusion (only sites generating randomisations as of May 17, 2021 are shown).

