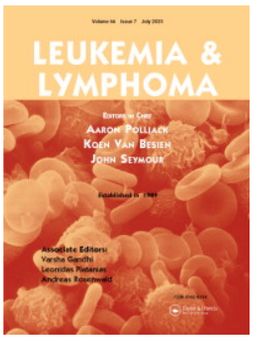


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# Treatment and outcome of breast implant-associated anaplastic large cell lymphoma: a population-based cohort study in the Netherlands

Frederik O. Meeuwes[a#], Mirian Brink[a,b#], Marjolein W. M. van der Poel[c], Y. I. M. Serroukh[d], Joost S. P. Vermaat[e], Gerwin A. Huls[a], Mintsje de Boer[f], Daphne de Jong[g], Wouter J. Plattel[a] and Marcel Nijland[a]

[a]Department of Hematology, University Medical Center Groningen, Groningen, The Netherlands; [b]Department of Research and Development, Netherlands Comprehensive Cancer Organization (IKNL), Utrecht, The Netherlands; [c]Department of Internal Medicine, Division of Hematology, GROW School for Oncology and Developmental Biology, Maastricht University Medical Center, Maastricht, The Netherlands; [d]Department of Hematology, Erasmus MC Cancer Institute, University Medical Center Rotterdam, Rotterdam, The Netherlands; [e]Department of Hematology, Leiden University Medical Center, Leiden, The Netherlands; [f]Department of Plastic Surgery, Maastricht University Medical Center, Maastricht, The Netherlands; [g]Department of Pathology, the Netherlands Cancer Institute, Amsterdam, The Netherlands

**ABSTRACT**

The optimal treatment of patients with breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) that underwent incomplete resection, have advanced stage disease or relapse after resection remains unknown. We describe the treatment and outcome of all 91 Dutch BIA-ALCL patients up to 2023. Primary outcomes were progression-free survival (PFS) and overall survival (OS). Ann Arbor stage I was frequently encountered (74%) compared to stage II (13%) and stage IV (11%). First-line treatment of stage I patients consisted mostly of surgery (88%). Stage II patients were treated with chemotherapy (CT) (67%) or underwent surgery (33%). All stage IV patients received CT. In total, 30% of patients ($n$=27) received CT. Relapse frequently occurred (60%) in stage IV disease. The 2-year PFS and OS for stage I, II and IV were 89 and 98%, 83 and 92% and 50 and 90%, respectively. Following second-line treatment, all but one patient remained in remission.

**HIGHLIGHTS**

We analyzed all 91 patients with breast-implant associated anaplastic large cell lymphoma in the Netherlands, showing excellent long term overall survival for all patients. However, still 30% was treated with chemotherapy and although relapse is frequent in stage IV disease, salvage therapy was highly successful, in contrast to other peripheral T-cell lymphomas.

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## Introduction

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a rare peripheral T-cell lymphoma (PTCL) associated with textured silicone breast implants (SBI). BIA-ALCL patients may have had a breast reconstruction with SBI due to breast cancer, prophylactic mastectomy for high breast cancer risk or for cosmetic reasons. The first BIA-ALCL case was reported in the United States in 1997 [1]. Since then, the Food and Drug Administration (FDA) of the United States of America has received reports on 1,380 unique cases worldwide until June 2024 [2]. Presentation is most commonly with seroma, although swelling or a peri-implant mass/lump can also be seen. BIA-ALCL cells are anaplastic lymphoma kinase (ALK) negative (-) and per definition express CD30 [3–10]. In a Dutch study, the cumulative risk of BIA-ALCL in women with implants was 29 per million at 50 years and 82 per million at 70 years (all the patients from that cohort are included in this study as well) [11].

For disease staging, the TNM-classification rather than the Ann Arbor (AA) staging classification for lymphoma is advocated since it has a better prognostic value [5]. The vast majority of patients present with limited stage (LS) disease, meaning that involvement is confined to the breast (AA stage I and TNM stage I-IIA) [5–7].

**CONTACT** Marcel Nijland m.nijland@umcg.nl University Medical Center Groningen, University of Groningen, Groningen, Department of Hematology, Hanzeplein 1, DA21, 9713 GZ, Groningen, The Netherlands.
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[#]These authors share first authorship

Nearly all patients with LS disease can be successfully treated with surgery alone. Surgical treatment consists of total en-bloc capsulectomy with explantation and is the mainstay of treatment in BIA-ALCL [5,8–10]. Incomplete resection is associated with a 5-year recurrence rate of 89% versus 4% among patients with complete resection and thus indicates the need for additional treatment [5].

For patients who have undergone incomplete resection, have advanced stage disease with lymph node involvement and/or organ involvement, or those who relapse after resection there is no standard of care. There are no prospective trials available in advanced stage (AS; meaning AA stage II or IV, or TNM stage IIB-IV) BIA-ALCL. Due to a limited number of patients, it is unlikely that such a trial will be performed. Patients with AS disease are treated mostly by means of surgical resection, combined with either chemotherapy, radiotherapy or a combination of both and sometimes undergo consolidative autologous stem cell transplant (ASCT) [5,13]. In the absence of prospective trials, chemotherapeutic treatment of BIA-ALCL is according to regimens that are used in PTCL and consists of cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP) either with or without the addition of etoposide (CHOEP) [6,9,12,14,15]. Concerning the common PTCL entities, only ALK positive (+) ALCL patients seem to have benefit from CHOEP over CHOP [16–21]. Moreover, ASCT is offered to fit patients with PTCL in first remission [20,22–25]. The role of etoposide and ASCT in BIA-ALCL is unknown.

Thus far, the only prospective phase 3 trial investigating a new first-line treatment in PTCL that has shown superiority over CHOP was the ECHELON-2 study, where CHOP was compared with the CD30 antibody-drug conjugate brentuximab vedotin (BV) combined with CHOP without vincristine (BV-CHP). BIA-ALCL patients were not included in this study [26]. However, because of the consistent CD30 positivity in BIA-ALCL, patients with stage IV BIA-ALCL might also benefit from BV-based regimens. Indeed, several case reports show response to BV monotherapy [27,28].

We conducted a nationwide, population-based cohort study with the aim to describe the clinical characteristics, treatment strategies and outcome of all patients with BIA-ALCL in the Netherlands.

## Material and methods

### Registry

The nationwide population-based Netherlands Cancer Registry (NCR) is maintained and hosted by the Netherlands Comprehensive Cancer Organization (IKNL) and has nationwide coverage of at least 95% of all malignancies since 1989 [29]. The NCR relies on comprehensive case notification through the Nationwide Histopathology and Cytopathology Data Network and the Nationwide Registry of Hospital Discharges (i.e. inpatient and outpatient discharges). Information on dates of birth and diagnosis, sex, topography and morphology, prior malignancies, hospital type of diagnosis, and first-line therapy is routinely recorded by trained registrars of the NCR through retrospective medical records review. For this study, we recorded detailed information on treatment characteristics, response and subsequent treatment lines and outcomes with ≥ 2 years of follow-up post-diagnosis for all Dutch BIA-ALCL patients. Information on last known vital status for all patients (i.e. alive, dead, or emigration) is obtained through annual linkage with the Nationwide Population Registries Network that holds vital statistics on all residents of the Netherlands.

### Study population

All newly diagnosed patients ≥ 18 years with BIA-ALCL up to 2023 were identified in the Netherlands Cancer Registry (NCR), using the International Coding system of Disease – Oncology (ICD-O) of the World Health Organization (WHO), morphology code 9715/3. Cases were centrally reviewed by an experienced hematopathologist (DJ). Survival follow-up was available through February 1, 2024 (patients alive were censored on this date). In lymphoma, the Ann Arbor (AA) staging system is used. Therefore, cases are registered in the NCR with AA stage, although at present the TNM-classification seems more appropriate to stage BIA-ALCL. Due to the definition of the breast being an extranodal site, it is not possible to have AA stage III disease with BIA-ALCL. Stage IA (T1N0M0), IB (T2N0M0), IC (T3N0M0) and IIA (T4N0M0) equal AA stage I, stage IIB (T1-3N1M0) and III (T4N1-2M0) equal AA stage II and stage IV (T1-4N0-2M1) equals AA stage IV. In this study, the AA staging system is used and when stage is mentioned, AA stage is meant. Overall response rate (ORR) was defined as partial remission (PR) or complete remission (CR). Patients were categorized according to first-line treatment regimen, i.e. surgery, chemotherapy (CT), CT with ASCT and/or radiotherapy (RT). Treatment in second-line was categorized correspondingly. According to the Central Committee on Research involving Human Subjects (CCMO), this type of observational study does not require approval from an ethics committee in the Netherlands. The Privacy Review Board of the NCR approved the use of anonymous data for this study.

### Endpoints

The primary endpoints were overall survival (OS) and progression free survival (PFS). OS was defined as the time interval between date of diagnosis of BIA-ALCL and all-cause death. PFS was defined as the time interval between diagnosis of BIA-ALCL and first date of relapse or all-cause death, whichever occurred first. Relapse was determined as a recurrence of disease after achieving CR following completion of first-line treatment. Patients who failed to adequately respond to first-line treatment or showed progressive disease (PD) were classified as primary refractory.

### Statistical analysis

Descriptive statistics were used to present patient and treatment characteristics, i.e. the Pearson chi-square test was used to compare categorical covariables, and the Kruskal–Wallis test was used to compare non-normally distributed continuous covariables between stage I, II and IV in first-line. A $p$-value <0.05 was considered statistically significant. The Kaplan-Meier method served to estimate OS and PFS, and the log-rank test to examine differences in survival distributions. OS and PFS was calculated overall as well as for the 2 treatment groups, i.e. surgery and CT. All analyses were performed using STATA/SE 17.1 (StataCorp LP, College Station, Texas, USA). The impact of age at diagnosis (per year increment), stage and prior diagnosis of breast cancer on risk of relapse and mortality was evaluated using uni- and multivariable Cox proportional hazard regression analysis. The results from the Cox regression analyses produce hazard ratios (HRs) with associated 95% confidence intervals (CIs). The proportional hazard assumption was tested based on the Schoenfeld residuals. Covariables were introduced in the regression models with a backward selection method. The final model was accomplished when the $p$-value for the covariables was below 0·05.

## Results

### Patient characteristics

Between January 1st 1997 and December 31st 2022, 91 patients with BIA-ALCL were registered in the NCR. The median age of these patients—all women—was 55 years (range 28-80 years). Stage I disease was diagnosed in 67 patients (74%), stage II in 12 patients (13%), stage IV disease in 10 patients (11%) and stage was unknown in 2 patients (2%) (Supplementary Table 1). Moreover, 33 patients (36%) had a prior diagnosis of breast cancer and 7 patients (8%) a prior malignancy other than breast cancer. The median time between breast cancer and BIA-ALCL diagnosis, when applicable, was 14.1 years (range 3.7-35.5 years). Over time, there was an increase in average annual incidence from 0.6 diagnoses per year in 1997-2007 to six diagnoses per year in 2008-2022. In the five most recent years of the study period, the average annual incidence increased to 9 patients (Supplementary Figure 1).

### Treatment

Overall, 64 patients (70%) underwent surgery and 27 patients (30%) were treated with CT. Of the 67 patients with BIA-ALCL stage I, 59 patients (88%) underwent explantation and capsulectomy and eight patients (12%) received CT. Of the twelve patients with stage II disease, four patients (33%) underwent surgery and eight patients (67%) received CT of whom one patient was consolidated with ASCT. All ten patients with stage IV BIA-ALCL received CT and two of these patients were treated with consolidative ASCT. One of the two patients with an unknown stage BIA-ALCL received CT, while the other patient underwent surgery (Figure 1).

Of the 27 patients who received CT, the majority ($n = 25$) were treated with a CHOP-based regimen (93%) of whom 25% including etoposide (CHOEP). For three patients, anthracyclines were replaced with etoposide during treatment (11%).

### Outcome

The ORR after first-line treatment – concerning the whole cohort – was 98%. PD during first-line treatment was observed for two patients (2%) with stage I disease. Among the 27 patients treated with CT, nineteen patients (70%) achieved CR, two patients (7%) partial remission (PR), one patient (4%) had PD and for five patients (19%), response was unknown (Figure 2). In total, twelve patients relapsed after CR (13%); five patients with stage I disease, one patient with stage II disease and six patients with stage IV disease. The median time to relapse after CR was 12 months following diagnosis (range, 4-87 months).

The 2-year PFS was 84%. Regarding stage of disease, 2-year PFS was 89%, 83% and 50% for stages I, II and IV disease, respectively (Figure 3(A)). Until February 1st 2024, one patient with stage I disease, two patients with stage II disease and two patients with stage IV disease died of unknown causes outside hospital-setting.

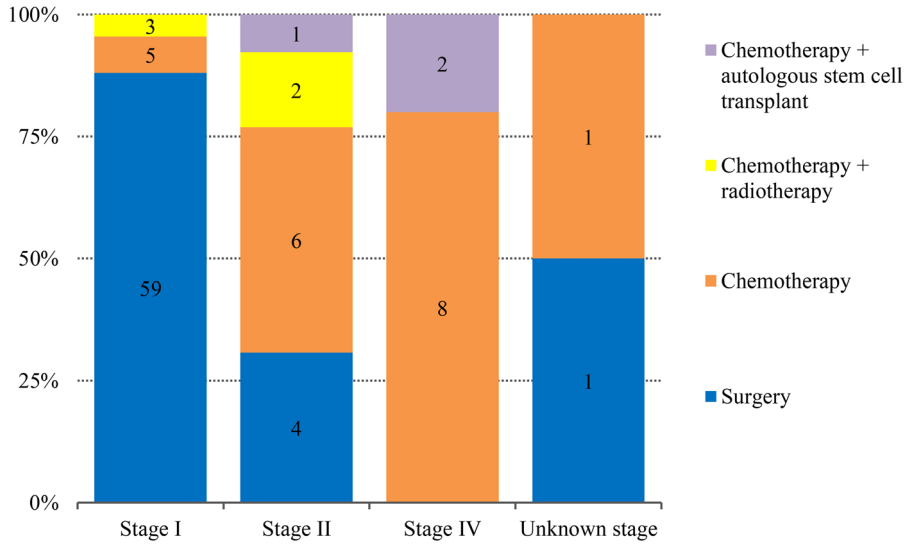


**Figure 1.** Treatment regimen of all patients with BIA-ALCL in The Netherlands according to stage. Abbreviations: CT: chemotherapy; ASCT: autologous stem cell transplantation; RT: radiotherapy.

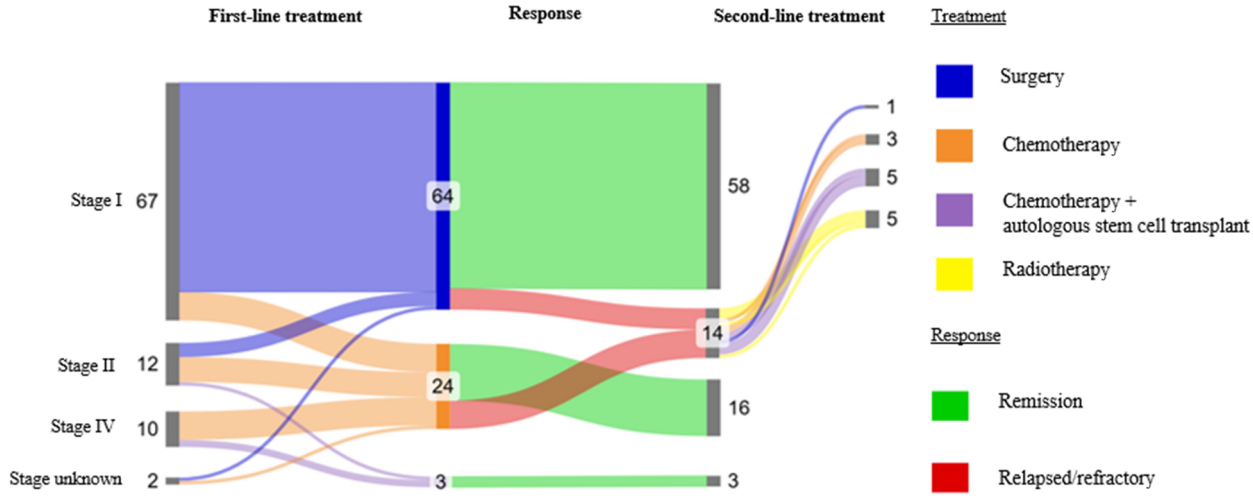


**Figure 2.** First- and second- line treatment of patients with BIA-ALCL.

The 2-year, 5-year and 10-year OS was 97%, 95% and 92%, respectively. The 2-year OS for stage I, II and IV were 98%, 92%, and 90%, respectively. The 10-year OS estimates were 98%, 73% and 80%, respectively (Figure 3(B)).

In uni- and multivariable analyses, stage IV disease (versus stage I disease) was associated with a higher risk of relapse (HR, 6.07; 95% CI, 2·34-15·75; $p < 0·01$), and mortality (HR, 11.78; 95% CI, 1·06-131·19; $p = 0·045$; Supplementary Table 2).

### *Second-line treatment for relapsed patients*

PD or relapse was observed in 14 patients until February 1st, 2024. The relapse rates (RR; including PD and relapse) were 15%, 10%, 8% and 60% for the whole cohort, stage I, stage II and stage IV, respectively. Of the four patients with stage I who relapsed after resection only in first-line, one received CT and three RT as second-line treatment. Of the remaining three patients with stage I, two received CT and consolidation with ASCT, and one RT in second-line. One patient with stage II disease received RT in second-line. Among six patients with stage IV who all received CT in first-line, five were treated with CT in second-line of whom three were consolidated with ASCT. One patient underwent surgery (Figure 2). With a median follow-up after relapse of 82 months (range, 4 – 280 months) all but one of relapsed patients remained in remission following second-line treatment.

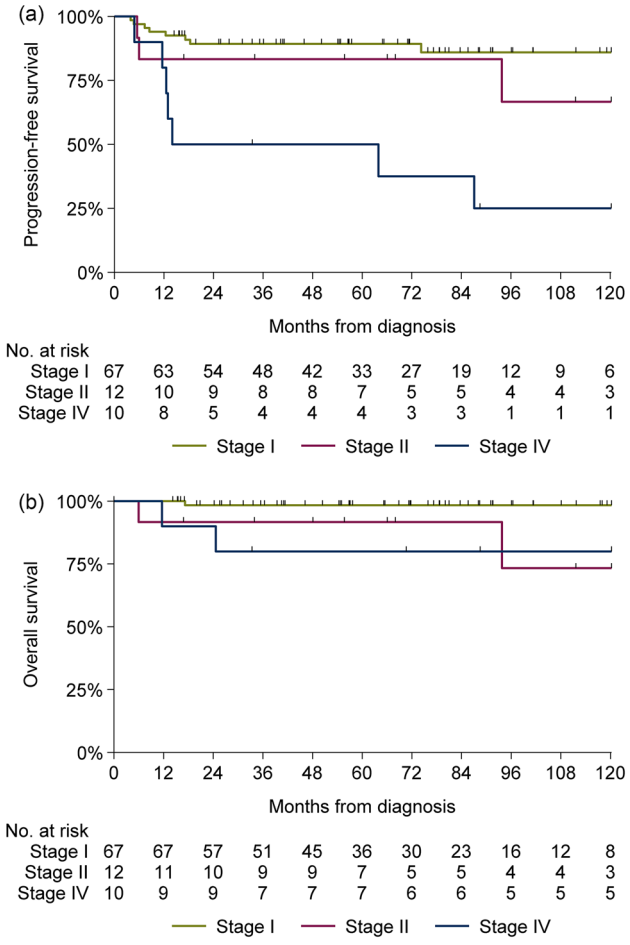


**Figure 3.** Survival of patients with BIA-ALCL diagnosed between 1997 and 2022. In panel A, progression-free survival is presented according to ann arbor stage I, II or IV (unknown stage was excluded) and in panel B overall survival. In both panels, Kaplan-Meier-curves are presented according to ann arbor stage (unknown stage was excluded)

## Discussion

The incidence of BIA-ALCL in the Netherlands is rising since the first reported case in 1997, although stage II-IV is only infrequently encountered (24%). Despite the encouraging outcome in stage I BIA-ALCL, as much as 30% of all BIA-ALCL patients received CT, most commonly in stage II and IV. The most commonly used regimen was CHOP, sometimes with the replacement of doxorubicin by etoposide, probably due to prior exposure and concern of exceeding the recommended maximum cumulative anthracycline dose.

Patients with stage I disease have an excellent 2-year PFS of 89% following resection and a 10-year OS of 98%. Although the 2-year OS was still 90%, 60% of stage IV patients relapsed. Patients with stage II and IV who relapsed after first-line treatment were generally treated with second-line CT and some underwent ASCT. In total, all but one patient remained in remission after second-line treatment, which is in strong contrast to other PTCL subtypes that show high relapse rates after salvage treatment [30]. Although five patients died during follow up, only one patient with stage IV disease had known progressive disease. Due to the nature of our study, cause of death is unfortunately unknown. However, this makes death of other causes than lymphoma likely in four out of five patients.

The low rate of AS versus LS disease that we observed was similar to previous observations [5,13,31]. The majority of patients mentioned in previous reports received chemotherapy, from 58%-65%, even though 53-83% had stage I disease and in one cohort even 10% underwent ASCT [5,13]. In contrast, only 5% of patients with stage I disease received chemotherapy in our study and 3% underwent ASCT, with generally excellent outcomes. On the other hand, still 30% of patients in our cohort received CT. Clemens et al. described a cohort of 87 BIA-ALCL patients. The 5-year OS was 89%, similar to the 95% in our study [5]. Limiting the exposure of chemotherapy and especially anthracyclines (doxorubicin) in these patients needs to be strongly considered due to its potential cardiotoxic effects. Furthermore, a markedly increased breast cancer risk in Hodgkin's lymphoma survivors treated with doxorubicin was found, whereby the cumulative incidence of breast cancer exceeds 20% [32].

In the most common subtypes of PTCL, CHOEP instead of CHOP only seems beneficial in the treatment of ALK+ ALCL [16–21]. Although BIA-ALCL is per definition ALK-, there is insufficient evidence to draw conclusions on the use of etoposide in BIA-ALCL. The use of ASCT seems beneficial in many subtypes of PTCL, although in BIA-ALCL there is little evidence to currently support its use in first line. However, among patients with BIA-ALCL stage IV, the relapse rate was high and the majority of patients responded either to salvage therapy or radiotherapy whereby the 10-year OS remained 80% [18,20,22–25 .Future studies might further determine the role of etoposide or consolidative ASCT in first-line treatment of stage IV BIA-ALCL patients to overcome the high relapse rate. As stated in the introduction, the antibody-drug conjugate brentuximab vedotin is also a very promising treatment option that warrants further investigation in BIA-ALCL due to its superiority over CHOP in the treatment of systemic ALCL, the fact that BIA-ALCL is CD30+ and case reports have shown encouraging results [26–28].

The strength of our study is that we were able to use a nationwide population-based cancer registry with comprehensive data available including first- and subsequent treatment lines and outcome of this rare disease. Moreover, this is the largest cohort of BIA-ALCL patients

published up to now where treatment details have been described and analyzed. It is one of the few studies that holds information on those with advanced stage disease from a hematologist's perspective. Limitations of our study include the lack of information on nonmalignant comorbidities and the lack of motivation on treatment decisions by clinicians. Although this is a large cohort of BIA-ALCL patients, numbers remain small. Nevertheless, cases could have been missed either due to an incorrect diagnosis or due to failing to register a case in the NCR (although the latter is unlikely, see Methods section). Despite its limitations, cancer registries remain the standard for cancer surveillance activities and for population-based analysis of treatment outcomes and are especially valuable in rare malignant diseases where no prospective trials are to be expected.

## Conclusion

In BIA-ALCL, long-term OS is excellent, although 30% of patients received chemotherapy. Relapse is frequent in stage IV disease, although salvage therapy was successful in most patients. There is a need for novel first-line treatment strategies in stage II-IV disease. However, patients with stage I disease should not be overtreated.

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## Author contributions

FM, MN and MB designed the study. MB collected and validated the data. MB, MN and FM analyzed the data. FM, MB and MN wrote the paper. All authors revised the manuscript and accepted its final version.

## Disclosure statement

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## ORCID

Frederik O. Meeuwes http://orcid.org/0000-0001-8264-8182
Mirian Brink http://orcid.org/0000-0002-6014-4810
Marjolein W. M. van der Poel http://orcid.org/0000-0002-1305-4150
Y. I. M. Serroukh http://orcid.org/0000-0001-8751-5725
Joost S. P. Vermaat http://orcid.org/0000-0002-1628-6256
Gerwin A. Huls http://orcid.org/0009-0001-6789-6433
Mintsje de Boer http://orcid.org/0000-0001-7214-0713
Daphne de Jong http://orcid.org/0000-0002-9725-4060
Wouter J. Plattel http://orcid.org/0000-0001-9828-9460

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