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Axillary surgery in breast cancer with one to three sentinel node macrometastases and breast-conserving surgery: Secondary results of the INSEMA trial

Toralf Reimer[1], Angrit Stachs[1], Kristina Veselinovic[2], Thorsten Kühn[2,3], Jörg Heil[4,5], Silke Polata[6], Frederik Marmé[7], Elisabeth Trapp[8], Thomas Müller[9], Guido Hildebrandt[10], David Krug[11], Beyhan Ataseven[12], Roland Reitsamer[13], Sylvia Ruth[14], Hans-Joachim Strittmatter[15], Carsten Denkert[16], Inga Bekes[2,17], Nicole Stahl[18], Dirk Michael Zahm[19], Marc Thill[20], Michael Golatta[4,5], Johannes Holtschmidt[21], Michael Knauer[22], Valentina Nekljudova[21], Sibylle Loibl[21,23], Bernd Gerber[1]

on behalf of the INSEMA investigators

1 Department of Obstetrics and Gynecology, University of Rostock, Germany; 2 Department of Obstetrics and Gynecology, University Hospital Ulm, Germany; 3 The Filderhospital, Filderstadt-Bonlanden, Germany; 4 Breast Center of St. Elisabeth Hospital, Heidelberg, Germany; 5 Department of Gynecology and Obstetrics, University of Heidelberg, Germany; 6 Evangelical Forest Hospital Spandau, Germany; 7 Faculty of Medicine Mannheim, University Heidelberg, Department of Obstetrics and Gynecology Mannheim, Germany; 8 Department of Obstetrics and Gynecology, University Hospital, Graz, Austria; 9 Department of Obstetrics and Gynecology, Hanau City Hospital, Hanau, Germany; 10 Department of Radiotherapy and Radiation Oncology, University Medicine Rostock, Germany; 11 Department of Radiotherapy and Radiation Oncology, University Hospital Hamburg-Eppendorf (UKE), Germany; 12 Bielefeld University, Department of Obstetrics and Gynecology, Klinikum Lippe, Germany; 13 University Hospital Salzburg, Department of Senology, Salzburg, Austria; 14 Johanniter-Hospital Genthin-Stendal, Germany; 15 Rems-Murr-Hospital, Winnenden, Germany; 16 Institute of Pathology, Philipps-University Marburg and University Hospital Marburg (UKGM)—University Hospital Marburg, Germany; 17 HOCH Health Ostschweiz, Kantonsspital St. Gallen, Universitäres Lehr- und Forschungsspital, Brustzentrum, St. Gallen, Switzerland; 18 Breast Unit, Helios Clinic, Schwerin, Germany; 19 SRH Wald-Klinikum Gera GmbH, Germany; 20 Agaplesion Markus Hospital, Frankfurt am Main, Germany; 21 GBG c/o GBG Forschungs GmbH, Neu-Isenburg, Germany; 22 Tumor and Breast Center Eastern Switzerland, St. Gallen, Switzerland; 23 Goethe University Frankfurt, Germany.

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Deutsche Krebshilfe HELFEN. FORSCHEN. INFORMIEREN.

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Disclosure Information

Toralf Reimer

I have the following relevant financial relationships to disclose:

Employee of: Department of Obstetrics and Gynecology, University of Rostock, Germany

Consultant for: Menarini, MSD, Myriad

Speaker's Bureau for: Astra Zeneca, Daiichi-Sankyo, MSD, Novartis, Pfizer, Roche

Grant/Research support from: German Cancer Aid, Else Kroener-Fresenius-Foundation, German Society of Senology

Stockholder in: none

Honoraria from: Pfizer

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All payments to the University Medicine Rostock (UMR), Germany.

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Background

- INSEMA Rando2 is one of the ongoing ACOSOG Z0011 validation trials evaluating sentinel lymph node biopsy (SLNB) alone versus completion axillary lymph node dissection (cALND) in patients with breast-conserving surgery (BCS) and involved sentinel lymph nodes (SLNs).
- Results of the SINODAR-ONE[1] and SENOMAC[2] studies showed that SLNB alone in patients with tumor stages T1-T3 is not inferior to cALND in case of 1-2 macrometastases in the SLNs.
- Previously, we reported primary and secondary outcomes of the INSEMA trial:
  - omission of axillary surgery did not result in inferior invasive disease-free survival (iDFS) compared to the standard SLNB in early breast cancer with BCS (INSEMA Rando1)[3]
  - insights of applied postoperative radiotherapy (Rando1)[4,5]
  - patient-reported outcomes (PROs) with Quality-of-Life data results showed that patients with no SLNB benefited regarding arm symptoms and functioning[6]
- **Goal of the INSEMA Rando2 is to demonstrate that SLNB alone does not result in inferior iDFS compared to the cALND in pN1a(sn) breast cancer with BCS.**

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1 Tinterri et al. Ann Surg Oncol 2022
2 de Boniface et al. NEJM 2025
3 Reimer et al. SABCS 2024; NEJM 2025
4 Hildebrandt et al. Int J Radiat Oncol Biol Phys 2020
5 Hildebrandt et al. SABCS 2025 (GS02-03)
6 Reimer et al. EClinicalMedicine 2022

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Study Design INSEMA Trial

≥18 years,
cT1/2 (≤5 cm), cN0,
planned BCS and
postoperative irradiation

N=5,230
per protocol

Rando 1:4

no SLNB
(n≈1,046)

SLNB
(n≈4,184)

SLN 1-3 involved nodes (n≈1,050):
Second rando (1:1): cALND vs SLNB alone

+ n≈800 entering the INSEMA Rando2 without being randomized in the main trial

Primary objective:

- To compare iDFS after BCS (non-inferiority question) between no axillary surgery and SLNB patients (first randomization)

Key secondary objective:

- To compare iDFS after BCS between SLNB alone and completion ALND patients (second randomization)

iDFS, invasive disease-free survival; BCS, breast-conserving surgery;
SLNB, sentinel lymph node biopsy; cALND, completion axillary lymph node dissection

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Methods

- The analysis of the initially co-primary end point was performed **on the per-protocol (PP) set** due to the non-inferiority study design[1].
- Kaplan-Meier product-limit method was used to estimate 5-year iDFS rates (reported with the two-sided 95% CI).
- **The non-inferiority was tested based on the CI of the hazard ratio (HR) from the Cox proportional hazard model to exclude the HR of 1.271 for the co-primary objective.**
  - **corresponding to the absolute decrease in 5-year iDFS rate from 81% (cALND arm) to 76.5% (SLNB only).**
- The target number of 1,968 patients was not achieved:
  - the sentinel node-positivity rate for 1-3 macromets was lower (11.3%) than expected (25.0%),
  - the recruitment rate directly into Rando2 was below the planned numbers,
  - the Z0011 publications of long-term FU data[2,3] led to modifications in German guidelines favoring SLNB alone.
- **> The Rando2 objective was downgraded to a secondary outcome** without statistical assumptions following the IDMC recommendation (protocol amend. #5; Dec 2018).

1 European Medicines Agency: ICH Topic E 9 statistical principles for clinical trials
2 Giuliano et al. Ann Surg 2016
3 Giuliano et al. JAMA 2017

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Consort Flow Diagram

478 patients in Rando1 ITT set were eligible for second randomization

33 were excluded from second randomization
- 7 had 3 positive LN (before AM4)
- 18 underwent ALND prior second randomization
- 6 based on investigator´s decision
- 2 withdrew consent

445 were randomized with preceding first randomization

40 were directly randomized into the second randomization

A total of 485 underwent second randomization

99 were excluded from the PP population
- 80 underwent axillary surgery not according to randomized arm
- 18 did not receive postoperative radiotherapy
- 1 had cN+ (iN+ status without FNA performed)

485 were included in the **intention-to-treat population**
- Completion ALND **N=243**
- SLNB alone **N=242**

386 were included in the **per-protocol population**
- SLNB alone **N=217**
- Completion ALND **N=169**

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Baseline Characteristics: Per-Protocol set

16.6% were aged <50 years

93.4% had HR+/HER2- subtype

Parameter	Category	SLNB alone N=217 N(%)	cALND N=169 N(%)
Age	median 59.0 years; (IQR: 52.0-68.0)		
	<65 years	140 (64.5)	111 (65.7)
	≥65 years	77 (35.5)	58 (34.3)
Preop. tumor size	≤2 cm	174 (80.2)	139 (82.2)
	>2 cm	43 (19.8)	30 (17.8)
Grading	G1	63 (29.0)	45 (26.6)
	G2	143 (65.9)	115 (68.0)
	G3	11 (5.1)	9 (5.4)
Ki-67 index	≤20%	176 (84.6)	128 (76.6)
	>20%	32 (15.4)	39 (23.4)
ER/PgR	both negative	5 (2.3)	2 (1.2)
	ER and/or PgR positive	212 (97.7)	167 (98.8)
HER2 status	negative	205 (94.9)	162 (95.9)
	positive	11 (5.1)	7 (4.1)

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Treatment Characteristics: Per-Protocol set

Mean number of dissected SLNs was 2.4 (median 2.0)

Mean number of dissected LNs in the case of cALND was 13.2 (median 13.0)

Parameter	Category	SLNB alone N=217 N(%)	cALND N=169 N(%)
Pathol. tumor size	pT1	130 (59.9)	99 (58.6)
	pT2	84 (38.7)	68 (40.2)
	pT3	3 (1.4)	2 (1.2)
Involved SLNs	**1**	**171 (78.8)**	**127 (75.2)**
(only macromets)	**2**	**41 (18.9)**	**34 (20.1)**
	3	**5 (2.3)**	**8 (4.7)**
All involved LNs	1-3		150 (88.8)
(SLNB + cALND)	4-9		19 (11.2)
Chemotherapy	**No**	**144 (66.4)**	**100 (60.2)**
	Yes	**73 (33.6)**	**66 (39.8)**
Endocrine therapy	No	9 (4.1)	9 (5.5)
	Yes	208 (95.9)	156 (94.5)
RNI* performed	**No**	**100 (79.4)**	**57 (64.0)**
	Yes	**26 (20.6)**	**32 (36.0)**
	Pts before amend. #4 (Mar 2017)	**91**	**80**

(*RNI, regional nodal irradiation)

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Secondary Endpoint: PP Analysis iDFS

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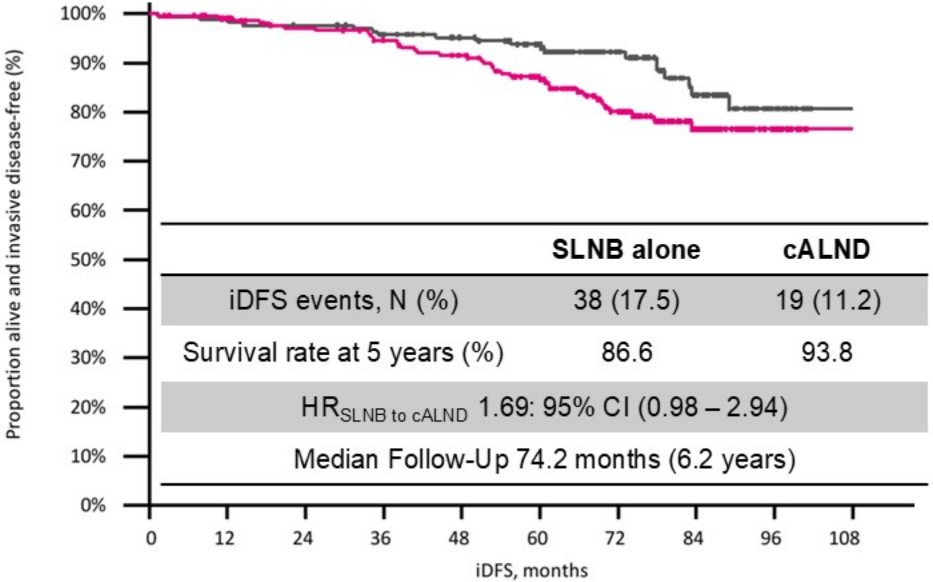
Confidence interval for the HR lies above the non-inferiority margin of 1.271

➢ **non-inferiority could not be shown**



	SLNB alone	cALND
iDFS events, N (%)	38 (17.5)	19 (11.2)
Survival rate at 5 years (%)	86.6	93.8
$HR_{\text{SLNB to cALND}}$ 1.69: 95% CI (0.98 – 2.94)		
Median Follow-Up 74.2 months (6.2 years)		

	0	12	24	36	48	60	72	84	96	108
completion ALND	169	165	162	154	143	126	80	46	15	0
SLNB only	217	205	195	186	176	146	96	47	13	0

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Secondary Endpoint Events (N=57)

Parameter	Category	SLNB alone N=38, N(%)	cALND N=19, N(%)	Overall N=57, N(%)
iDFS event	**Invasive locoregional recurrence**	**4 (1.9)**	**2 (1.2)**	**6 (1.6)**
	- Axillary recurrence	1 (0.5)	0 (0.0)	1 (0.3)
	- Invasive ipsilateral breast recurrence	3 (1.4)	2 (1.2)	5 (1.3)
	Invasive contralateral BC	1 (0.5)	0 (0.0)	1 (0.3)
	Distant relapse	**15 (6.9)**	**7 (4.1)**	**22 (5.7)**
	Secondary malignancy	9 (4.1)	4 (2.4)	13 (3.4)
	Death	9 (4.1)	6 (3.6)	15 (3.9)

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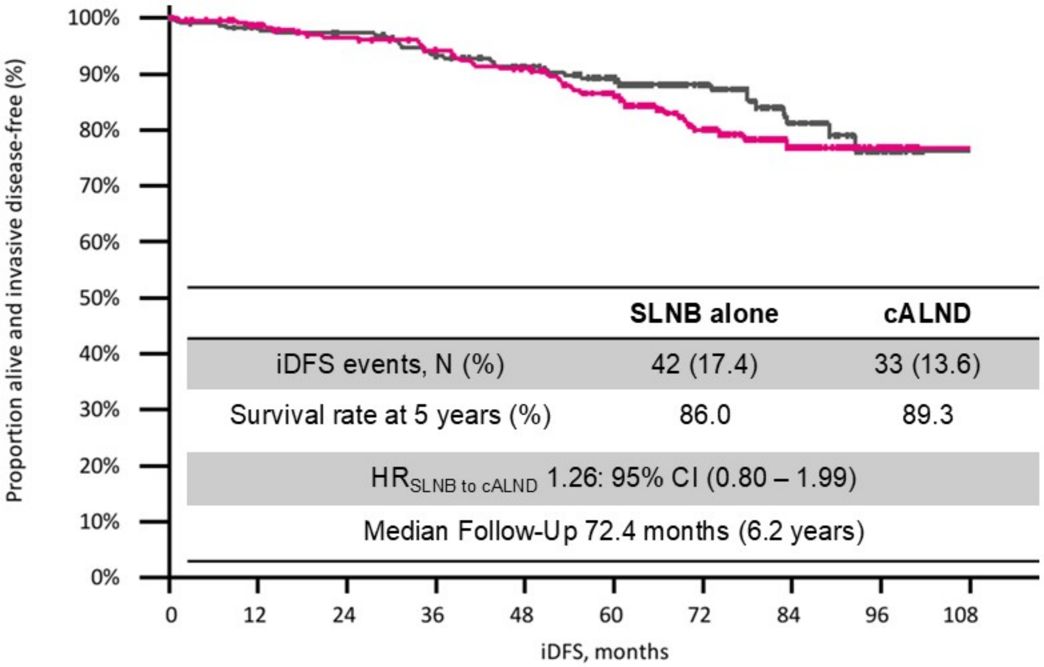
Secondary Endpoint: ITT Analysis iDFS

Confidence interval for the HR lies above the non-inferiority margin of 1.271

- ➢ **non-inferiority could not be shown**



	SLNB alone	cALND
iDFS events, N (%)	42 (17.4)	33 (13.6)
Survival rate at 5 years (%)	86.0	89.3
$HR_{SLNB\ to\ cALND}$ 1.26: 95% CI (0.80 – 1.99)		
Median Follow-Up 72.4 months (6.2 years)		

	0	12	24	36	48	60	72	84	96	108
completion ALND	243	221	215	200	184	159	103	56	18	0
SLNB only	242	226	214	203	192	159	106	52	15	0

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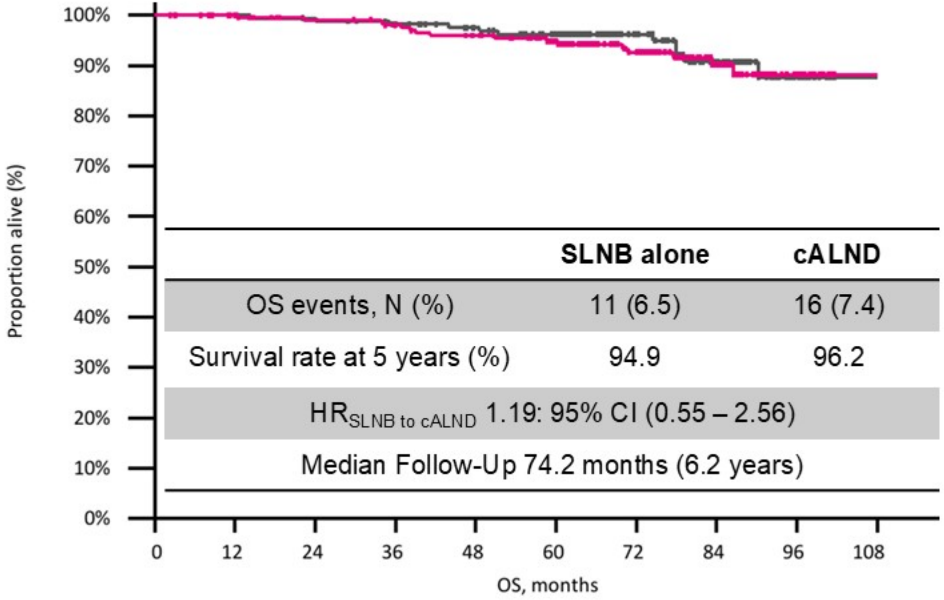
Overall Survival: Per-Protocol Analysis



	SLNB alone	cALND
OS events, N (%)	11 (6.5)	16 (7.4)
Survival rate at 5 years (%)	94.9	96.2
$HR_{SLNB\ to\ cALND}$ 1.19: 95% CI (0.55 – 2.56)		
Median Follow-Up 74.2 months (6.2 years)		

	0	12	24	36	48	60	72	84	96	108
completion ALND	169	167	165	157	146	129	83	49	17	0
SLNB only	217	207	198	192	183	158	113	59	18	0

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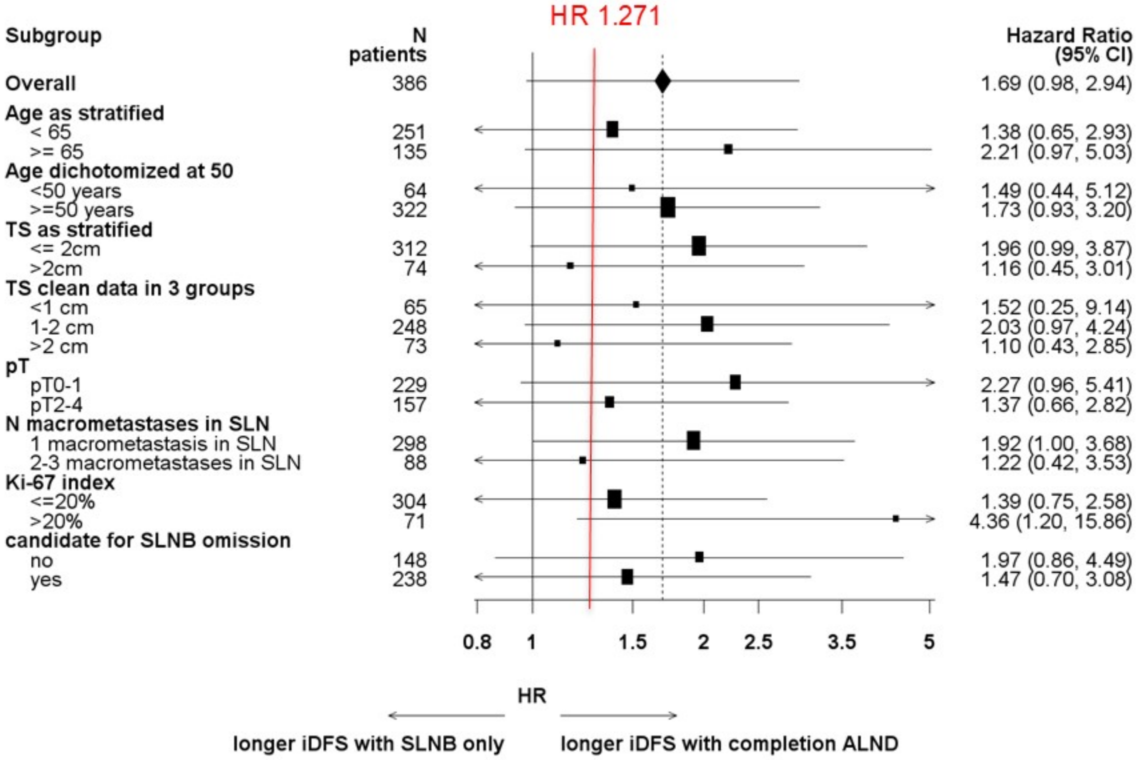
Invasive Disease-Free Survial in Subgroups



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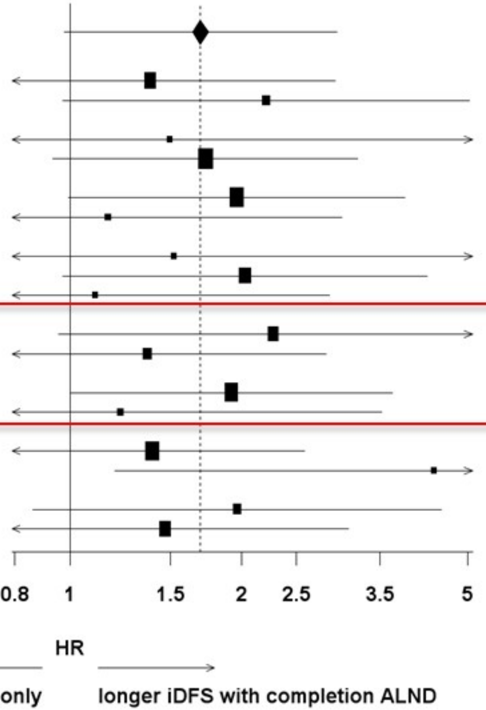
Invasive Disease-Free Survial in Subgroups

Subgroup	N patients	Hazard Ratio (95% CI)
Overall	386	1.69 (0.98, 2.94)
Age as stratified		
< 65	251	1.38 (0.65, 2.93)
>= 65	135	2.21 (0.97, 5.03)
Age dichotomized at 50		
<50 years	64	1.49 (0.44, 5.12)
>=50 years	322	1.73 (0.93, 3.20)
TS as stratified		
<= 2cm	312	1.96 (0.99, 3.87)
>2cm	74	1.16 (0.45, 3.01)
TS clean data in 3 groups		
<1 cm	65	1.52 (0.25, 9.14)
1-2 cm	248	2.03 (0.97, 4.24)
>2 cm	73	1.10 (0.43, 2.85)
pT		
pT0-1	229	2.27 (0.96, 5.41)
pT2-4	157	1.37 (0.66, 2.82)
N macrometastases in SLN		
1 macrometastasis in SLN	298	1.92 (1.00, 3.68)
2-3 macrometastases in SLN	88	1.22 (0.42, 3.53)
Ki-67 index		
<=20%	304	1.39 (0.75, 2.58)
>20%	71	4.36 (1.20, 15.86)
candidate for SLNB omission		
no	148	1.97 (0.86, 4.49)
yes	238	1.47 (0.70, 3.08)



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Invasive Disease-Free Survial in Subgroups

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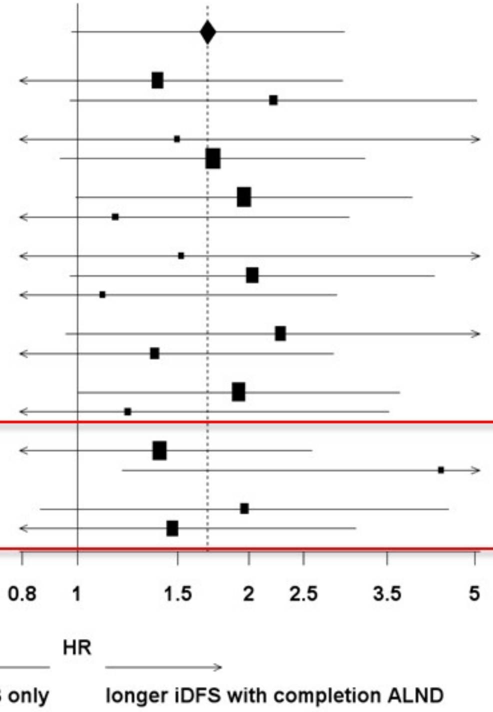

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RT-Parameters – 2nd Randomization: PP set

Parameter	Category	SLNB alone N=217 N (%)	cALND N=169 N (%)	p-value
RT-technique	- 3D-CRT (tangential fields)	120 (56.1)	96 (56.8)	0.996
	- IMRT / VMAT	49 (22.8)	40 (23.6)	
	- Simultaneous integrated boost	25 (11.7)	18 (10.7)	
	- Deep inspiration breathhold	6 (2.8)	4 (2.4)	
	- Other	14 (6.5)	11 (6.5)	
Fractionation	- conventional	**157 (75.1)**	**147 (87.0)**	**0.004**
	- hypofractionation	**52 (24.9)**	**22 (13.0)**	
Boost	- yes	**175 (80.6)**	**150 (88.8)**	**0.035**
	- no	**42 (19.4)**	**19 (11.2)**	
Boost technique	- External beam (3D-CRT)	87 (50.6)	75 (50.7)	0.762
	- External beam (IMRT/VMAT)	37 (21.5)	32 (21.6)	
	- External beam (Electrons)	8 (4.7)	3 (2.0)	
	- Intraoperative (Electrons)	7 (4.1)	11 (7.4)	
	- Intraoperative (Photons)	3 (1.7)	2 (1.4)	
	- Interstitial brachytherapy	4 (2.3)	4 (2.7)	
	- Other	26 (15.1)	21 (14.2)	

No differences in axillary radiotherapy dose (levels I-III) were detected between study arms.

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Strengths & Limitations

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Strengths & Limitations

- Data are based on the longest median follow-up and the highest axillary tumor burden of all Z0011 validation trials.
- The median follow-up and patient's numbers with macrometastases (ITT cohort) are comparable with the first analysis of ACOSOG Z0011 trial.
- Prospective assessment regarding incidental axillary irradiation dose during WBI

Strengths & **Limitations**

- The planned target recruitment number for the second randomization was not achieved.
- Major crossover between per-protocol and ITT cohorts lead to incongruent results comparing 5-year iDFS rates.
- Significant differences regarding postoperative radiotherapy between study arms (fractionation schedule, boost application, and RNI)

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Conclusion

- INSEMA Rando2 provides additional data on the oncological safety of patients with cALND omission following a positive SLNB during BCS, with a strict indication for RNI and radiotherapy quality assurance.
- No significant differences were observed between SLNB alone vs. cALND in both subsets (PP, ITT) for iDFS, OS, and locoregional recurrence.
- For the first time, our results suggest a potential impact of omission of the cALND on the 5-year iDFS (non-inferiority of SLNB alone could not be demonstrated):
  - This finding can be explained in part by differences in radiotherapy parameters, chemotherapy application rates, and an unexpected effect of a high Ki-67 index.
- Regarding overall survival, the primary end point of the Z0011 trial, our secondary outcome analyses confirm the previous data.
- The follow-up will continue, and 10-year FU data are expected for 2029.

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- All patients and their families, all participating sites, and IDMC

Cooperating partners

Collaborating study groups:

AGO-B BREAST STUDY GROUP

NOGGO NORDOSTDEUTSCHE GESELLSCHAFT FÜR GYNÄKOLOGISCHE ONKOLOGIE

ABCSG AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

SUCCESS

WSG Westdeutsche Studiengruppe West German Study Group

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GBG

Members of the Subboard GBG and AGO-B

PM and Monitoring:
Teresa Jeri, Margit Simon, Udo Pfeil

Translational Research:
Bärbel Felder, Christiane Rothhaar, Stefanie Lettkemann

Data Management:
Britta Hormann, Keyur Mehta

Medical Team:
Natalie Donde, Nader Hirmas

Medical Writing:
Alena Leunov

GBG GERMAN BREAST GROUP