

Dear Study Sites, dear Friends and Supporters of the MELODY Study,

with this second international MELODY newsletter, we would like to inform you about the current recruitment status of the study, organizational news, and scientific activities of the MELODY Study Group.

You can also find important information and files for download at our website: <http://eubreast.org/melody>

On behalf of the International Steering Board and the Organizing Committee,

Prof. Dr. Maggie Banys-Paluchowski
 Prof. Dr. Thorsten Kühn
 Prof. Dr. Jana de Boniface
 Rajiv Dave
 Dr. Oreste Davide Gentilini

Prof. Bahadır M. Güllüoğlu
 Prof. Dr. med. Markus Hahn
 James Harvey
 Prof. Dr. G. Karadeniz Çakmak
 Dr. Andreas Karakatsanis

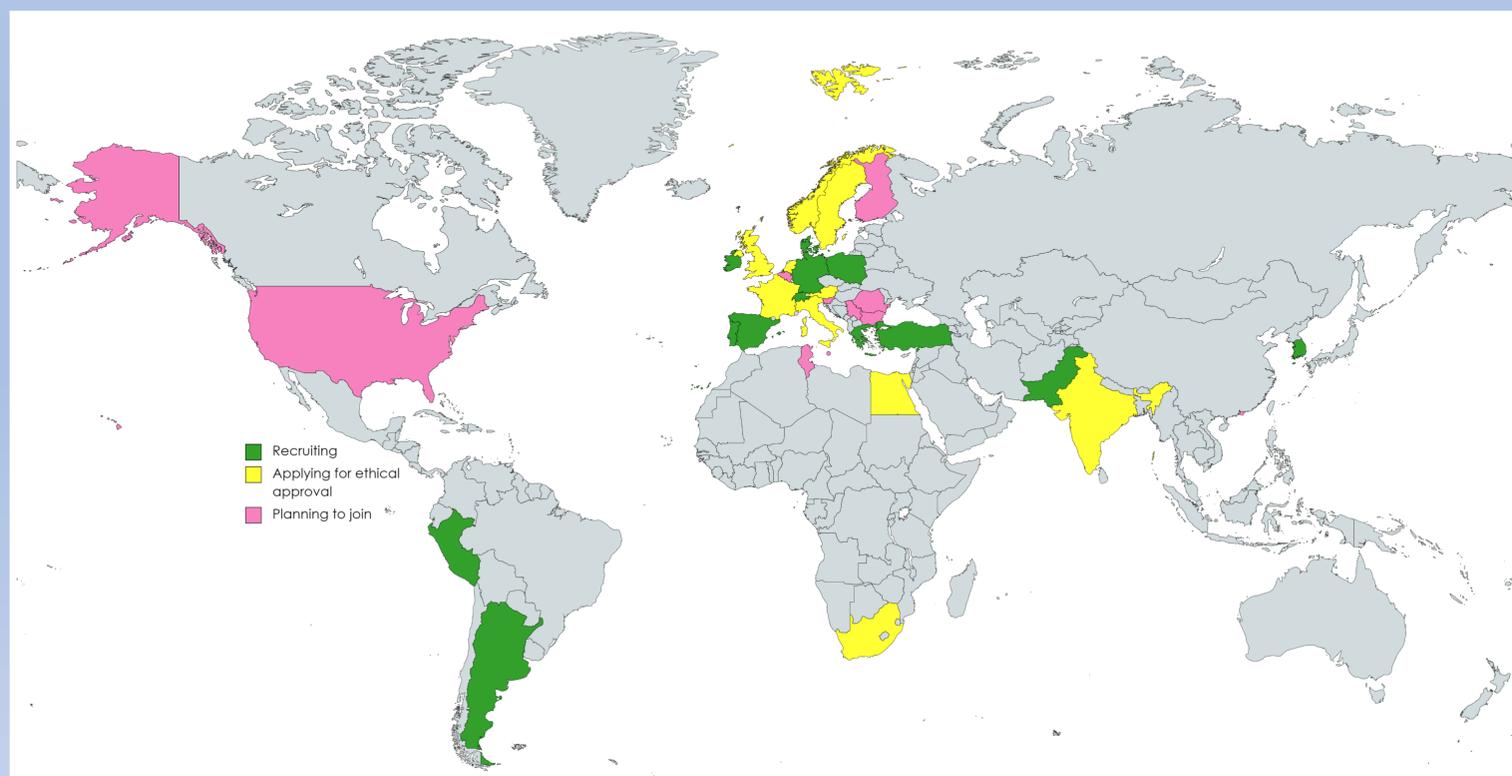
Dr. Ash Kothari
 Prof. Dr. med. Michael Lux
 Shelley Potter
 Dr. Isabel Rubio
 Prof. Marjolein Smidt

Prof. Dr. Walter Weber
 Dr. Yazan Masannat
 Prof. Dr. Nina Ditsch
 PD Dr. Steffi Hartmann
 PD Dr. Natalia Krawczyk

Enrollment status

Currently, 42 study sites are open in ten countries. We congratulate the National Steering Committees of the following countries, which enrolled at least one patient:

- **Denmark** (Dr. Tove Filtenborg Tvedskov, Dr. Lina Pankratjevait)
- **Germany** (Prof. Dr. Nina Ditsch, PD Dr. Steffi Hartmann, PD Dr. Natalia Krawczyk)
- **Greece** (Prof. Michalis Kontos)
- **Ireland** (Prof. Dr. Aoife Lowery)
- **Pakistan** (Prof. Mah Muneer Khan, Dr. Irum Sabir Ali)
- **Peru** (Dr. Lia Pamela Rebaza)
- **Poland** (Prof. Dawid Murawa, Dr. Justyna Jelinska)
- **Spain** (Dr. Antonio Esgueva, Dr. Isabel Rubio)
- **Switzerland** (Dr. Maria Luisa Gasparri, Prof. Walter Weber)
- **Turkey** (Prof. Neslihan Cabioglu & Prof. Zafer Canturk)



MELODY Initiation presentation

The study sites are kindly asked to participate in an initiation presentation. The next international initiation presentation in English will take place on **20th March (Wednesday) 2024 at 7 p.m. CET (Time Zone Berlin, Paris, Madrid, Rome) = 6 p.m. London** (please check your local time!)

Zoom link:

<https://us02web.zoom.us/j/88113136284>

Meeting-ID: 881 1313 6284

You can also visit our website to see the recorded initiation videoconference (link: <http://eubreast.org/melody>)

Korea joins MELODY!



We are very proud that the Korean Breast Cancer Study Group decided to support MELODY! Prof. Dr. Jai Min Ryu, MD, PhD leads the National Steering Committee and plans to join the study with 18 sites.

San Antonio Breast Cancer Symposium 2023

The concept of the MELODY study has been presented at several national conferences and recently in the „Ongoing Trials“ session at the SABCS in December 2023. You can see all publications from the study at:

<http://eubreast.org/melody> / Publications

Methods for Localization of Different Types of Breast Lesions
A prospective non-interventional multicenter cohort study to evaluate different imaging-guided methods for localization of malignant breast lesions (EUBREAST-4/IBRA-NET, NCT05559411)

Abstract #P04-18-12; San Antonio Breast Cancer Symposium, December 5-9, 2023

Study Lead: EUBREAST / IBRA-NET (Intergroup Study)
Study design: Prospective non-interventional multicenter cohort study (IT)
Target accrual: 7,416 patients
Enrollment begin: January 2023
Current status (Nov 2023): 37 open study sites in 18 countries

Financial support: Endomag, Merit Medical, Sirius Pintulion and Hologic

Why do we need the MELODY study?
In the last decades, the proportion of patients with breast cancer receiving breast-conserving surgery has increased, reaching 70-80% in developed countries. In case of non-palpable lesions, surgical excision requires some form of breast localization. While wire-guided localization has long been considered gold standard, it carries several limitations, including logistical difficulties, the potential for displacement and patient discomfort, and re-excision rates reaching 21%. Other techniques have been developed with the aim of overcoming these disadvantages (Fig. 2). However, comparative data on the rates of successful lesion removal, negative margins and re-operations are limited. In most studies, patients' perspective with regard to discomfort and pain level has not been evaluated. The aim of MELODY is to compare different localization methods with regard to oncological safety, patient-reported outcomes, and surgeon and radiologist satisfaction.

Primary outcomes
• Intended target lesion and/or marker removal
• Negative resection margin rates (defined as lesion removal with no invasive or non-invasive carcinoma on ink) at first surgery

Secondary outcomes
Second surgery – Secondary mastectomy – Re-resection Ratio – Duration of surgery – Marker placement failure – Localization failure – Patient-reported outcomes (e.g., patient discomfort, pain level, and impairment of breathing) – Diagnostician/radiologist's satisfaction – Surgeon's satisfaction – "Lost markers" – Volume and weight of resected tissue – Learning curve – Impact of self-reported ethnicity on other outcome measures – Economic resources – Economic impact (cost-benefit analysis) – MRI artifacts – Complication rates

Inclusion criteria
• Malignant breast lesion requiring breast-conserving surgery and imaging-guided localization (DCIS or invasive; multiple or bilateral lesions and the use of neoadjuvant chemotherapy are allowed)
• Planned surgical removal of the lesion using one or more of the following imaging-guided localization techniques:
✓ Wire-guided localization
✓ Intraoperative ultrasound
✓ Magnetic localization
✓ Radioguided occult lesion localization (ROLL)
✓ Radioactive seed localization
✓ Radar localization
✓ Radiofrequency identification (RFID) tag localization
✓ Ink/carbon localization

Fig. 2. Examples of different detection methods for breast lesions.
Imaging (panoramic/mammogram), Wire-guided localization, Intraoperative ultrasound, Magnetic localization, Radioactive seed localization, Radar localization, Radiofrequency identification (RFID) tag localization, Ink/carbon localization

Fig. 3. Current status of international participation.
Green: Recruiting
Yellow: Awaiting for ethical approval
Pink: Planning to join

For more information, visit: <http://eubreast.org/melody>

MELODY Study Group: Verónica Yamila Fabiano^{1*}, Jai Min Ryu^{2*}

Enrollment status

	Enrolled patients	Open study sites
Total	554	42
Denmark	110	1
Germany	106	8
Greece	19	1
Ireland	7	1
Pakistan	20	1
Peru	8	1
Poland	77	1
Spain	6	3
Switzerland	28	6
Turkey	173	19

International MELODY Teams

Country	Heads (underlined) & Members of the National Steering Committee
Argentina	<u>Dr. Verónica Yamila Fabiano</u> , Laura Cosaka
Austria	<u>Prof. Florentia Peintinger</u> , Dr. Angelika Rief
Denmark	<u>Dr. Tove Filtenborg Tvedskov</u> , Dr. Lina Pankratjevaite, Dr. Panagiotis Pappas
Egypt	<u>Dr. Khaled Abdelwahab</u>
France	<u>Dr Séverine Alran</u> , Dr Noémie Lotersztajn, Dr Marion Cortet, Dr Parwana Zarka, Dr Marie Rose El Bejjani, Dr Sophie Beranger
Germany	<u>Prof. Dr. Nina Ditsch</u> , PD Dr. Steffi Hartmann, PD Dr. Natalia Krawczyk
Greece	<u>Prof. Michalis Kontos</u>
India	<u>Prof. S.V.S. Deo</u>
Ireland	<u>Prof. Aoife Lowery</u>
Italy	<u>Dr. Rosa di Micco</u>
Korea	<u>Prof. Dr. Jai Min Ryu</u>
Pakistan	<u>Prof. Mah Muneer Khan</u> , Dr. Irum Sabir Ali
Peru	<u>Lía Pamela Rebaza, M.D.</u>
Poland	<u>Prof. Dawid Murawa</u> , Dr. Justyna Jelinska
Portugal	<u>Maria Antónia Vasconcelos, MD</u> , Dr. David Pinto
South Africa	<u>Dr Sarah Nietz & Dr Francoise Malherbe</u>
Spain	<u>Dr. Antonio Esgueva</u> , Dr. Isabel Rubio
Sweden	<u>Dr. Andreas Karakatsanis</u> , Prof. Dr. Jana de Boniface
Switzerland	<u>Dr. Maria Luisa Gasparri</u>
Turkey	<u>Prof. Neslihan Cabioglu & Prof. Nuh Zafer Canturk</u>
United Kingdom	<u>Dr Yazan Masannat</u>

<http://eubreast.org/melody>

Enrollment status by site

Study Site	Country	Principle Investigator	Enrollment
Copenhagen University Hospital	Denmark	Lina Pankratjevaite	110
Zonguldak Bulent Ecevit University The School of Medicine	Turkey	Guldeniz Karadeniz Cakmak	81
Department of Surgical Oncology University Hospital of Zielona Gora	Poland	Dawid Murawa	77
University Hospital Schleswig-Holstein Campus Lübeck	Germany	Maggie Banyas-Paluchowski	74
Istanbul University-Istanbul Faculty of medicine	Turkey	Neslihan Cabioglu	44
Khyber Medical College & Khyber Teaching Hospital	Pakistan	Mah Muneer Khan	20
1st Dept. of Surgery, University of Athens - "Laiko" General Hospital	Greece	Michalis Kontos	19
Sakarya University	Turkey	Belma Kocer	16
Marienhospital Bottrop	Germany	Hans-Christian Kolberg	15
Koc University Hospital	Turkey	Ece Dilege	15
EWK Spandau	Germany	Silke Polata	11
Ente Ospedaliero Cantonale, Dep. Gynecology and Obstetrics	Switzerland	Maria Luisa Gasparri	10
Kantonsspital St. Gallen	Switzerland	Inga Bekes	8
Clinica Oncosalud Auna	Peru	Pamela Rebaza	8
Brustzentrum Lindenhofgruppe	Switzerland	Gilles Berclaz	7
Galway University Hospital	Ireland	Aoife Lowery	7
Hospital Universitario La Paz	Spain	Laura Frias Aldeguer	5
Ondokuz Mayıs University Samsun	Turkey	Ayfer Kamali	5
Christliches Klinikum Unna Mitte	Germany	Cristin Kühn	4
Istanbul University Oncology Institute	Turkey	Hasan Karanlik	4
basaksehir cam and sakura city hospital	Turkey	Ebru Sen	4
Universitätsspital Basel	Switzerland	Martin Heidinger	3
Liv Hospital Vaci Istanbul	Turkey	Seyma Karakus Bozkurt	3
Kreisklinik Ebersberg gGmbH	Germany	Stephan Hasmüller	2
Clínica Universidad de Navarra	Spain	Antonio J. Esgueva	1
Kocaeli University School of medicine	Turkey	Nuh Zafer Canturk	1
UFK am Klinikum Südstadt Rostock	Germany	Steffi Hartmann	0
GRN Klinik Weinheim	Germany	Lelia Bauer	0
Christophorus Kliniken Coesfeld; Brustzentrum Münsterland	Germany	Carmen Shulte-Tiwisina	0
Insel Gruppe AG	Switzerland	Claudia Rauh	0
Brust-Zentrum AG	Switzerland	Christoph Tausch	0
Hospital Clinico Universitario de Valencia	Spain	Elvira Buch Villa	0
Acibadem University School of medicine Department	Turkey	Cihan Uras	0
Univercity Health Science Ankara Oncology Training and Research Hospital Department of Surgical Oncology	Turkey	Lüfti Dogan	0
University of Health Science Gülhane Reserarch and Training Hospital	Turkey	Mehmet Ali Gülcelik	0
Bezmialem Vakif University Medical Faculty	Turkey	Yeliz Emine Ersoy	0
Istanbul Demiroglu Bilim University, Faculty of Medicine, General Surgery	Turkey	Enver Özkurt	0
Baskent University Adana Teaching Hospital	Turkey	Hüseyin Özgür Aytac	0
Istinye University, School of medicine, Liv Hospital Ulus	Turkey	Mehmet Levhi Akin	0
Bahcesehir University School of Medicine	Turkey	Didem Can Trabalus	0
Acibadem Altunizade Hospital	Turkey	Aykut Soyder	0
Sancaktepe Sehit Prof. Dr. Ilhan Varank Training and Research Hospital	Turkey	Nihan Turhan	0

IMPRESSUM

EUBREAST & iBRA-NET

Study coordination:

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Germany: Jana Shabbir: shabbir@eubreast.com

In case of questions: melody@eubreast.com



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