

# Collecting data on patients with a breast cancer who undergo or do not undergo magnetic resonance imaging (MRI) before surgery

<b>Submission date</b> 17/06/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/08/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/01/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Magnetic resonance imaging (MRI) using a contrast material is more effective than mammography (an X-ray of the breasts) in the measurement of tumor size as well as in diagnosing otherwise undetected tumors in the same or in the other breast. However, MRI may also detect benign lesions and additional cancers, prompting needle biopsies or surgical procedures which could be unnecessary. This international study is aimed at collecting data on patients with breast cancer who do or do not undergo MRI before surgery.

### Who can participate?

Women from 18 to 80 years of age with a newly diagnosed breast cancer.

### What does the study involve?

Data will be collected from all involved institutions on women with a newly diagnosed first breast cancer who either undergo or do not undergo preoperative MRI. Data on surgical outcomes of the MRI group will be compared to those obtained in the concurrent no MRI group. Each patient will undergo a contrast-enhanced preoperative breast MRI according to local clinical practice.

### What are the possible benefits and risks of participating?

Participating in this study does not imply any change in planned diagnostic and treatment protocols and no risks are associated with this study.

### Where is the study run from?

IRCCS Policlinico San Donato (Italy).

### When is the study starting and how long is it expected to run for?

The study will run from July 2013 to June 2018.

Who is funding the study?

The study is sponsored by the European Institute for Biomedical Imaging Research (EIBIR, Vienna, Austria) and supported by a research grant by Bayer Pharma AG, Berlin, Germany.

Who is the main contact?

Professor Francesco Sardanelli  
francesco.sardanelli@unimi.it

## Contact information

### Type(s)

Scientific

### Contact name

Prof Francesco Sardanelli

### Contact details

Unità di Radiologia, IRCCS Policlinico San Donato  
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20097

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

Preoperative breast MRI in clinical practice: Multicenter International Prospective metaAnalysis (MIPA) of individual woman data

### Acronym

MIPA

### Study objectives

The results of two randomized controlled trials concerning preoperative MRI were published, none of them in favor of the use of preoperative breast MRI. The results of both studies were unexpected and have not definitively solved the clinical issue of using or not using MRI for a preoperative evaluation of breast cancer. In fact, several limitations and criticisms were raised against both studies. Notwithstanding these results, preoperative breast MRI is increasingly

used in clinical practice. Thus, a systematic evaluation of preoperative breast MRI looking at the individual patient data in a multicenter international setting could clarify the above matters regarding the ongoing uncertainty on application of preoperative breast MRI.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Study firstly approved on January 29th, 2013 by the Comitato Etico Indipendente, ASL Milano Due (n. 2784) for the IRCCS Policlinico San Donato, Milan, Italy. Each center applied for approval from the relevant Ethical Committee (On June 11, 2013, a total of 23 centers had the study approved).

**Study design**

Observational multicenter longitudinal two-cohort study. Duration: 5 years.

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Other

**Participant information sheet**

[http://www.eibir.org/wp\\_live\\_eibir12\\_km21s/wp-content/uploads/2013/08/MIPA-Patient-Information-Sheet.pdf](http://www.eibir.org/wp_live_eibir12_km21s/wp-content/uploads/2013/08/MIPA-Patient-Information-Sheet.pdf)

**Health condition(s) or problem(s) studied**

Breast cancer

**Interventions**

Data on consecutive series of women with a newly diagnosed first breast cancer, not candidate to neoadjuvant chemotherapy, who undergo (MRI-group) or not (noMRI group) undergo preoperative MRI, will be prospectively and systematically collected from all involved institutions. Data on surgical outcomes of the MRI-group will be compared to those obtained in the concurrent noMRI group, matching for age (5year age strata), histology (invasive ductal versus invasive lobular) and analytically adjusting for covariates. Each patient will undergo a contrast-enhanced preoperative breast MRI according to local clinical practice.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Proportion of patients receiving reexcision due to positive or close surgical margins
2. Overall rate of unilateral (or bilateral) mastectomy

### **Secondary outcome measures**

1. Rate of change of surgical planning from that planned on basis of conventional imaging to that recommended on the basis of MRI findings in the MRI group
2. Ipsilateral recurrence during 5year followup
3. Contralateral breast cancer during 5year followup
4. Diagnosis of distant metastases (confirmed by at least two imaging techniques) during 5year followup

### **Overall study start date**

01/07/2013

### **Completion date**

30/06/2018

## **Eligibility**

### **Key inclusion criteria**

Women from 18 to 80 years of age with a newly diagnosed needlebiopsy proven first breast cancer

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Female

### **Target number of participants**

7,000 patients

### **Key exclusion criteria**

1. Pregnancy
2. Previous history of nonbreast cancer at any site
3. Previous history of breast cancer (invasive or DCIS)
4. Women candidates to neoadjuvant chemotherapy
5. Women with evidence of distant metastases at the time of breast MRI
6. Women with absolute contraindications to MRI or to gadoliniumbased contrast materials according to international guidelines or local regulations (including eGFR <30 ml/min\*1.73 m<sup>2</sup>)
7. Women who received any contrast material prior to breast MRI examination or are scheduled to receive any contrast material within 24 hour afterwards
8. Mental disability precluding informed consent to participate

**Date of first enrolment**

01/07/2013

**Date of final enrolment**

30/11/2018

## **Locations**

**Countries of recruitment**

Australia

Austria

Belgium

Brazil

Denmark

France

Germany

Hungary

Ireland

Italy

Netherlands

Russian Federation

Spain

Türkiye

United Kingdom

United States of America

**Study participating centre**

Unità di Radiologia, IRCCS Policlinico San Donato

San Donato Milanese

Italy

20097

## **Sponsor information**

**Organisation**

EIBIR, gemeinnützige Gmbh zur Förderung der Erforschung der biomedizinischen Bildgebung

**Sponsor details**

Neutorgasse 9/2

Vienna

Austria

1010

**Sponsor type**

Not defined

**Website**

<http://www.eibir.org/>

**ROR**

<https://ror.org/02svqt910>

**Funder(s)****Funder type**

Industry

**Funder Name**

Bayer Pharma AG, Germany (ref: 160411)

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration