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

Submission date 17/06/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/08/2013	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/01/2019	**Condition category** Cancer	[_] Individual participant data [_] 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
San Donato Milanese
Italy
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

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 MRIgroup
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 m2)
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