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Assessment of the impact of national breast cancer screening program in achieving downstaging of breast cancer and improving quality of life of breast cancer patients in Morocco

Submission date	Recruitment status	[_] Prospectively registered
02/05/2019	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
16/07/2019	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
11/07/2024	Cancer	

Plain English summary of protocol

Background and study aims
Morocco has set up a breast cancer screening program to ensure access to good quality early detection, diagnosis and treatment of breast cancer for all eligible women. The aim of this study is to assess whether this program has achieved downstaging of breast cancer and improved quality of life (QoL) of breast cancer patients by comparing the stage and the QoL of the breast cancer cases diagnosed through the program with those diagnosed outside the program (self-reported). In addition, the study will assess the access delay, diagnostic delay and treatment delay of the breast cancer patients at the major oncology centers in Morocco.

Who can participate?
Breast cancer patients registered with the oncology centers during the first two years of the study

What does the study involve?
Before starting treatment, the participants are interviewed by trained staff using a questionnaire to document the following information: basic personal data (contact details, age, residence, educational level, medical insurance, marital status, occupation), medical history and breast cancer screening history (the date and test results of the last breast examination). Breast cancer stage, lymph node status, immunohistochemistry status and type of treatment response and vital status data are also collected from their medical files. Participants are also interviewed using questionnaires to collect QoL data before the start of any treatment. At least 1 month after completion of definitive treatment and 1 year after completion of treatment, the QoL questionnaire is administered again to the same participants. The participants have to spend about 30 minutes during each visit.

What are the possible benefits and risks of participating?
The participants will not receive any direct benefit from the study. However, the study is of great public health importance. It will be helpful to know the impact of the ongoing screening programme in terms of stage distribution of the breast cancers, and the proportion of cancer patients requiring less radical surgeries and adjuvant treatment. Morocco is among the very few countries in the world that have implemented a nationwide clinical breast examination-based screening programme and it is important to assess the impact of such a programme. Early diagnosis and appropriate treatment at an early stage are likely to improve quality of life more significantly in those women detected and referred through the breast cancer screening programme. The study is expected to demonstrate this impact of screening program. There are no risks for research participants, but some of the participants may be embarrassed at responding to some of the personal questions. All the staff administering the QoL questionnaire are females and appropriately trained. The patient will always have the option of not responding to any particular question. Adequate privacy will be maintained during the interview.

Where is the study run from?
The study will be conducted in Morocco in two major oncology centres (Rabat and Casablanca) with specialized breast cancer management unit.

When is the study starting and how long is it expected to run for?
October 2018 to June 2022

Who is funding the study?
Cancer Research Institute (Morocco)

Who is the main contact?
1. Dr Partha Basu
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Assessment of the impact of national breast cancer screening program in achieving downstaging of breast cancer and improving quality of life of breast cancer patients in Morocco

Acronym
ImpactBCP

Study objectives
Morocco introduced the national breast cancer screening program in 2010. Trained nurses, midwives and general practitioners screen the women between 40 and 69 years of age for breast cancer by clinical breast examination (CBE) at the primary health centers (PHC). The screen-positive women are referred to the Cancer Early Detection Centers (CEDC) or the provincial hospitals for further assessment. The CEDC (total 27 across the country) are well-equipped to perform mammography, breast ultrasound, and breast core biopsy.

A recently completed review of the program performance jointly by IARC and the Lalla Salma Foundation for Cancer Prevention and treatment shows that in the year 2016 alone 1.6 million women were screened for breast cancer and 1,238 new cases of breast cancer were detected through the program. In spite of the opportunistic approach, the annual coverage of the target population for breast cancer screening exceeded 30%. This indicates that the program is on track to cover at least 60% of the entire target population defined by the Ministry of Health in a single biennial round of screening for breast cancer. For continued quality assurance, it is essential to assess the impact of the screening program on stage distribution of the breast

cancers, the proportion of cancer patients requiring less radical surgeries and adjuvant treatment and the quality of life of the patients. Such data, though difficult to obtain through a regular health information system within the program, will not only improve the quality of the screening program in Morocco but will also contribute to the evidence base supporting CBE screening in developing nations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 15/11/2018, IARC Ethics Committee (150 cours Albert Thomas, 69372 Lyon cedex 08, France; Tel: +33 (0)4 72 73 83 41; Email: iec-secretariat@iarc.fr), Ref IEC Project No. 18-05
2. Approved 26/07/2018, Ethics Committee for Rabat Biomedical Research (Impasse Souissi, Rabat, 10100, Morocco, Tel: +212 (0)537 77 35 60; Email: guedirak@yahoo.fr), Ref Dossier No. 112/8

Study design
Multicentre observational longitudinal study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Before initiation of treatment, the patients will be interviewed by trained staff using a questionnaire to document the following information: basic personal data (contact details, age, residence, educational level, medical insurance, marital status, occupation), medical history and breast cancer screening history (the date and test results of the last CBE screening). The recruited patients will be also interviewed before the initiation of any treatment using the third version of the QLQ-C30 and QLQ BR23 questionnaires of the European Organization for Research and Treatment of Cancer adapted to the local context to collect quality of life (QoL) data. At least one month after completion of definitive treatment and 1 year after completion of treatment, both quality of life questionnaires will be administered again to the same participants patients and received treatment and vital status data will be also collected from their medical files.

Intervention Type
Other

Primary outcome measure
1. Mean duration between detection by CBE (in the patients referred through screening program) or onset of symptoms (in the self-reported group) and date of registration at the cancer hospital (access delay); mean duration between registration and the confirmation of diagnosis (diagnosis delay); and mean duration between confirmation of diagnosis and onset of treatment (treatment delay): estimated using the data collected by a questionnaire which includes date of CBE, date of onset of symptoms, date registration at cancer center, date of confirmation of diagnosis and date of treatment onset.
2. Distribution of breast cancer stage (clinical TNM and pathology TNM), lymph node status, IHC status and type of treatment by the groups (screen-detected and self-reported breast cancer cases): reported using the data collected by a questionnaire which was designed to capture breast cancer stage (clinical TNM and pathology TNM), lymph node status, immunohistochemistry status and type of treatment at the time of the recruitment and the initiation of treatment.
3. Rate of breast preservation surgeries by groups (screen-detected and self-reported breast cancer cases): calculated using the data collected by a questionnaire which was designed to capture the type of surgery at the time of initiation of treatment.
4. Treatment response rate by groups (screen-detected and self-reported breast cancer cases): calculated using the data collected by a questionnaire which was designed to capture the treatment response one year after completion of treatment.
5. Functional dimensions and symptoms scores on QOL study and improvement between pre- and post-treatment scores by groups (screen-detected and self-reported breast cancer cases): measured using the QLQ-C30 and the EORTC QLQ-BR23 questionnaires of the European Organization for Research and Treatment of Cancer (EORTC) before the initiation of any treatment, 1 month after completion of definitive treatment and 1 year after completion of treatment.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/10/2018

Completion date
30/06/2022

Eligibility

Key inclusion criteria
Women registered with the histopathology diagnosis of breast cancer at the designated cancer centre(s) during the study period

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Estimation of 3,000 women with breast cancer

Total final enrolment
1081

Key exclusion criteria
Women in whom the final histopathology diagnosis will be benign disease; recurrent breast cancers

Date of first enrolment
01/05/2019

Date of final enrolment
27/08/2020

Locations

Countries of recruitment
Morocco

Study participating centre
National Institute of oncology Sidi Mohamed Ben Abdellah
Avenue Allal El Fassi
Rabat
Morocco
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Study participating centre
Mohammed VI centre for treatment of cancers of Casablanca
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Sponsor information

Organisation
International Agency For Research On Cancer

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Sponsor type
Research organisation

Website
https://www.iarc.fr/

ROR
https://ror.org/00v452281

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The Foundation Lalla Salma Cancer prevention and treatment

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Sponsor type
Charity

Website
http://www.contrelecancer.ma

Funder(s)

Funder type
Research organisation

Funder Name
Cancer Research Institute

Results and Publications

Publication and dissemination plan

The publication of the results is planned in a high-impact peer-reviewed journal and will be around one year after the overall trial end date. The researchers will follow the IARC open-access policy for journal publication and dissemination of the study results.
The protocol is available on request to basup@iarc.fr

Intention to publish date

30/09/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be not publicly available as per IARC policies. Proposals should be directed to the IARC principal investigator (PI) Dr Partha Basu (BasuP@iarc.fr). To gain access, data requestors will need to sign a data access agreement. The data will be shared with investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose. Individual participant data underlie the results reported in the published article after deidentification (text, tables, figures and appendices) will be shared. The data will be available from 9 months to 36 months following article publication. The data will be shared to achieve aims in the approved proposal.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/06/2024	11/07/2024	Yes	No