

**PLEASE NOTE:** *This trial has been registered retrospectively.*

## Trial Description

### Title

**COVID-19 pandemic and breast cancer management: An observational clinical study from Pakistan**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**COVID-19 outbreak has adversely affected care of breast cancer patients world-wide. There is paucity of available data on cancer management in lower-middle income countries during this pandemic, we sought to determine the institutional approach towards management of breast cancer patients and the outcomes during COVID-19 pandemic at our institution**

### Brief Summary in Scientific Language

**Background: COVID-19 outbreak has adversely affected care of breast cancer patients world-wide. There is paucity of available data on cancer management in lower-middle income countries during this pandemic, we sought to determine the institutional approach towards management of breast cancer patients and the outcomes during COVID-19 pandemic at our institution.**

**Materials and Methods: Clinicopathological and treatment record of cancer patients who presented to the Breast Clinic from 15th March to 31st July 2020 was retrieved from the institutional database for this retrospective clinical observational study.**

**Results: A total of 112 patients were qualified for the analysis in which 66 patients (58.9%) underwent breast cancer surgeries. Only 7 of them (10.6%) were identified to be COVID-19 virus positive on routine pre-operative RT-PCR test before elective surgeries. All were asymptomatic, received home-based care via telecommunication and were operated at a later date when test turned out negative. None of them developed any complications post-operatively. Another group of 44 patients (39.3%) were referred for Neoadjuvant/ Systemic chemotherapy in which COVID-19 infection was detected in only 3 patients (6.8%). Two patients shown symptoms of cough and fever hence hospitalised but were not candidates for Intensive Care Unit admission while the third patient was asymptomatic and isolated at home. All patients recovered well and chemotherapy was commenced again after negative RT-PCR test. No mortality was observed.**

**Conclusion: Despite of being a global crisis particularly for cancer patients we managed to keep infectivity, complications and fatality much lower among breast cancer cases**

### Do you plan to share individual participant data with other researchers?

**No**

### Description IPD sharing plan

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## Organizational Data

- DRKS-ID: **DRKS00023807**
- Date of Registration in DRKS: **2020/12/10**
- Date of Registration in Partner Registry or other Primary Registry: [---]\*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **No approval required according to EC**
- (leading) Ethics Committee Nr.: **2020-5418-14043 , Aga Khan University (ERC)Pakistan**

## Secondary IDs

## Health condition or Problem studied

- Free text: **COVID-19**
- ICD10: **C50 - Malignant neoplasm of breast**

## Interventions/Observational Groups

- Arm 1: **Patients with Breast cancer presented from March 15 2020 to July 30 20220 were tested for COVID-19 subsequently data was collected on Proforma.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
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Blinding: [---]\*

- Who is blinded: [---]\*
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

#### Primary Outcome

**COVID 19 Infectivity and associated complications in breast cancer cases.**

#### Secondary Outcome

**Overall outcome of breast cancer patients**

#### Countries of recruitment

- PK **Pakistan**

#### Locations of Recruitment

- University Medical Center **Aga Khan University**

#### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/03/14**
- Target Sample Size: **112**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

#### Inclusion Criteria

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Gender: **Both, male and female**

■ Minimum Age: **23 Years**

■ Maximum Age: **72 Years**

#### **Additional Inclusion Criteria**

**All Breast cancer patients who presented to Breast Clinic from 15th March to 31st July 2020 which either underwent surgery or referred for Neoadjuvant treatment were included.**

#### **Exclusion criteria**

**Those patients with incomplete medical records or lost to follow-up were excluded from the analysis**

#### **Addresses**

■ **Primary Sponsor**

**Aga Khan University**

**Ms. Assistant Professor Lubna Vohra**

**National Stadium Rd, Aga Khan University Hospital, Karachi, Pakistan.**

**74000 Karachi**

**Pakistan**

Telephone: **00923215303685**

Fax: [---]\*

E-mail: **lubna\_mushtaque at hotmail.com**

URL: [---]\*

■ **Contact for Scientific Queries**

**Aga Khan University**

**Mr. Dr Dua Jabeen**

**Rafiqi H.J, Iqbal Shaheed Rd, Karachi Cantonment, Karachi,**

**75850 Karachi**

**Pakistan**

Telephone: **00923212793106**

Fax: [---]\*

E-mail: **jabeen\_dua at hotmail.com**

URL: [---]\*

■ **Contact for Public Queries**

**Aga Khan University**

**Ms. DR Narmeen Asif**

**National Stadium Rd, Aga Khan University Hospital, Karachi, Pakistan.**

**74000 Karachi**

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**Aga Khan University**

**Ms. DR Narmeen Asif**

**National Stadium Rd, Aga Khan University Hospital, Karachi, Pakistan.**

**74000 Karachi**

**Pakistan**

Telephone: **0092322281056**

Fax: [---]\*

E-mail: **narmeen.asif at aku.edu**

URL: [---]\*

### Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

**Aga Khan University Hospital**

**Ms. Assistant Professor Lubna Vohra**

**National Stadium Rd, Aga Khan University Hospital, Karachi, Pakistan.**

**75850 Karachi**

**Pakistan**

Telephone: **00923215303685**

Fax: [---]\*

E-mail: **lubna\_mushtaque at hotmail.com**

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### Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2020/10/03**

### Trial Publications, Results and other documents

\* This entry means the parameter is not applicable or has not been set.

\*\*\* This entry means that data is not displayed due to insufficient data privacy clearing.