

Comparing the use of an Arabic decision aid to the usual care for Arabic-speaking metastatic colorectal cancer patients in Saudi Arabia

Submission date 17/12/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/02/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/02/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Colorectal cancer (CRC) ranks first in males and third in females among all cancers in Saudi Arabia (SA). CRC incidence and related deaths have been steadily increasing in SA over the past 20 years. Care for a metastatic colorectal cancer patient is a complex process. It could include chemotherapy, palliation, and surgery. The possible benefit frequently comes at the cost of toxicity, hospitalization, and sometimes-critical care. Previous studies reported that 28.2% of patients diagnosed were distant metastasis. Decision aids (DAs) are tools used to improve communicating information between health providers and patients and to involve patients in decisions about their health care. Cancer-related decisions can be difficult due to diagnosis anxiety, denial, and lack of effective communication. Several studies have shown that the use of decision aids help in improving patients' knowledge and satisfaction. Although the evidence of benefits of DAs is available for breast cancer and colon cancer patients, no study has been found to show the usefulness of an Arabic decision aids within the Arab culture. The aim of this study is to evaluate the effect of a decision aid (DA) designed for metastatic colorectal cancer patients in the Arabic language.

Who can participate?

Patients aged 21 to 75 attending the outpatient clinic newly diagnosed with metastatic colorectal cancer

What does the study involve?

Participants are randomly allocated to receive a visual decision aid tool alongside standard care or standard care alone (all information provided by physician). The researchers measure the effect on a patient's decision making, anxiety level and understanding of metastatic colorectal cancer.

What are the possible benefits and risks of participating?

There are no physical risks as this is a non-invasive study and the proposed benefits are that providing patients with diagnosis, prognosis and treatment options through a decision aid tool (visual tool) will improve patient decision making, lower anxiety and improve understanding.

Where is the study run from?

1. King Khalid University Hospital (Saudi Arabia)
2. King Fahd Medical City (Saudi Arabia)
3. King Saud Medical City (Saudi Arabia)
4. King Fahd Specialist Hospital (Saudi Arabia)

When is the study starting and how long is it expected to run for?
December 2014 to April 2019

Who is funding the study?

King Abdulaziz College of Science and Technology (Saudi Arabia)

Who is the main contact?

1. Dr Ayshah AlSaghier (Principal investigator)
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

#33-35

Study information

Scientific Title

Comparing the use of an Arabic decision aid to the usual care: a multicenter randomized controlled trial for Arabic-speaking metastatic colorectal cancer patients in Saudi Arabia

Study objectives

Are decision aids (DAs) more effective than the usual communication and decision-making practices for Arabic-speaking colorectal cancer patients?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16/12/2014, Ministry of Health, KFSH-D Institutional Review Board (IRB) (Research Executive Administration - King Khalid Medical City (REA-KKMC), King Fahad Specialist Hospital-Dammam, Bldg. 100, First Floor, Office 31, 28, Saudi Arabia;
Tel: +966 (0)38431111, ext. 2978-2904-2903; Email: IRB@kfsh.med.sa), National Registration Number H-05-D002

Study design

Prospective randomized two-arm parallel multi-center trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Metastatic adenocarcinoma of the colon or rectum

Interventions

Decision aids (DAs) are a tool used to improve communicating information between health providers and patients, and to involve patients in decisions about their health care.

Stratified randomization lists are computer-generated for allocation of each participant to a case or control arm. Healthcare providers are not blinded; oncologists and patients are informed of the randomization arm only when patients receive the DA. Those receiving DA are counselled not to share it with others in the waiting room to avoid contamination of information of the standard arm.

The researchers collect the demographic data and disease characteristics at baseline, along with patient response to anxiety survey. They survey patients immediately after the consultation about their understanding, anxiety, and satisfaction with decision-making. They indicate their initial learning toward a treatment decision. One month later the researchers survey again after the treatment decision regarding anxiety, knowledge, and we surveyed the oncologists about their satisfaction with the DA. At 6 months post-decision, the researchers surveyed the patients again about anxiety and their satisfaction with the decision.

Intervention Type

Other

Primary outcome(s)

Patient understanding of prognostic, treatment information and satisfaction with decision-making, assessed using a questionnaire that covers various content areas regarding colorectal cancer metastases, e.g., the natural history of colorectal cancer, the risk of cancer recurrence and, what chemotherapy is and how it is given, and the benefits and risks associated with chemotherapy. Each item on the questionnaire consists of a statement followed by a true/false/unsure response. A scoring instrument is used as the percentage of correct responses from 0–10. Measured immediately after the consultation and after 1 and 6 months.

Key secondary outcome(s)

1. Patient satisfaction with decision-making using the effective decision-making subscale of the Decisional Conflict Instrument at baseline, 1 and 6 months
2. Patient anxiety measured using Generalized Anxiety Disorder Scale (GAD-7) at baseline, 1 and 6 months
3. Patient understanding based on mCRC standard prognosis and treatment information at baseline and 1 month
4. Physician satisfaction measured using a combination of two surveys (pretrial survey)

Completion date

30/04/2019

Eligibility

Key inclusion criteria

1. Age between 21 and 75 years
2. Confirmed diagnosis of metastatic adenocarcinoma of the colon or rectum
3. Patient or companion must be able to read and write
4. Written informed consent is obtained from each patient

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Not candidate for chemotherapy because of medical reason or very poor performance status
2. Illiterate patient and companion have uncontrolled psychiatric condition or any other condition that impairs ability to decision making (e.g. dysphasia, deafness etc)
3. Life expectancy less than 6 weeks
4. Patients were excluded if they had previously received chemotherapy for metastatic colorectal cancer (adjuvant chemotherapy permitted), cognitive impairment with patient and companion, severe comorbid illness, or extreme anxiety or distress, as assessed by the treating physician

Date of first enrolment

01/03/2016

Date of final enrolment

30/10/2018

Locations**Countries of recruitment**

Saudi Arabia

Study participating centre

King Khalid University Hospital

King Saud University

Riyadh

Saudi Arabia

12372

Study participating centre

King Fahd Medical City

Makkah AlMukarramah Road

As Sulimaniyah Area

Riyadh

Saudi Arabia

59046

Study participating centre

King Saud Medical City

Al Imam Abdulaziz Ibn Muhammed Ibn Saud
Riyadh
Saudi Arabia
12746

Study participating centre**King Fahd Specialist Hospital**

AlMuraikebat Area, Ammar Bin Thabet Street
PO Box 15215
Dammam
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31444

Sponsor information

Organisation

Ministry of Health

ROR

<https://ror.org/01qe7f394>

Funder(s)

Funder type

University/education

Funder Name

King Abdullah University of Science and Technology

Alternative Name(s)

, KAUST

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Saudi Arabia

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication. The analysed data will be part of publication manuscripts.

IPD sharing plan summary

Other