Assessing the generalizability of all-cause mortality from the MOSAIC trial to older adults diagnosed with stage II and III colon cancer in SEER-Medicare (Generalizability of colon cancer trial results)

First published: 17/01/2018

Last updated: 02/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS22355

Study ID

22356

DARWIN EU® study

No

Study countries

☐ United States

Study description

In this study, we propose to apply generalizability weighting methods using data from older adults (age 65-75 years) enrolled in the MOSAIC randomized controlled trial (RCT) and SEER-Medicare observational cohort (a linkage of cancer registry and Medicare enrollment and claims data). Specifically, we aim to: (1) estimate the expected effects of adjuvant chemotherapy with oxaliplatin versus 5-fluorouracil (5-FU) alone in routine care populations of older adults (age 65-75 years) diagnosed with stage II and III colon cancer and (2) assess whether we can use the MOSAIC data to predict all-cause mortality in an observational SEER-Medicare cohort of older adults. We will conduct a cohort study using patient-level MOSAIC trial data and aggregated information from the SEER-Medicare database, providing the unique opportunity to pursue our aims. We will plan to present our research findings at scientific conferences and publish our results in a peer-reviewed journal.

Study status

Ongoing

Research institutions and networks

Institutions

University of North Carolina at Chapel Hill

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Institution

Department of Epidemiology

Contact details

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Primary lead investigator

Jennifer Lund

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 02/02/2017

Study start date

Actual: 02/02/2017

Date of final study report

Planned: 31/05/2018

Sources of funding

- Other

More details on funding

UNC Lineberger Comprehensive Cancer Center

Study protocol

CSDR_submission_Lund.pdf(257.46 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

Access to data for this study was approved and obtained via clinicalstudydatarequest.com (CSDR). Our proposal number on CSDR is 1660. https://www.clinicalstudydatarequest.com/

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

Specifically, we aim to estimate the expected effects of adjuvant chemotherapy with oxaliplatin versus 5-fluorouracil (5-FU) alone in routine care populations of older adults (age 65-75 years) diagnosed with stage II and III colon cancer.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Secondary analysis of a clinical trial, incorporating observational data

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

OXALIPLATIN

FLUOROURACIL

Medical condition to be studied

Colon cancer stage II

Colon cancer stage III

Population studied

Age groups

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

4500

Study design details

Outcomes

All-cause mortality

Data analysis plan

We will reweight the entire MOSAIC trial population (i.e. both arms) who are aged 65-75 years at randomization to reflect the distribution of key covariates of patients aged 65-75 years with stage II and III colon cancer in the SEER-Medicare cohort initiating oxaliplatin (i.e. age at diagnosis, sex, stage of cancer (AJCC stage, substage), tumor size, (T1-4), lymph node involvement (0, 1, or 2+), differentiation (well, moderately, poor), and perforation (yes vs. no). We will then estimate the 3- and 5-year risk difference and 3- and 5-year risk ratio for all-cause mortality corresponding to the estimated “treatment effect in the treated” overall and by stage. We will use a similar weighting method to estimate a treatment effect in all patients who receive any treatment (or the estimated “treatment effect in the population”).

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No