Study of Adjuvant Nivolumab or Placebo in Subjects With Resected Esophageal or Gastroesophageal Junction Cancer (CheckMate 577)

This study is currently recruiting participants. (see Contacts and Locations)

Verified September 2016 by Bristol-Myers Squibb

Sponsor:
Bristol-Myers Squibb

Information provided by (Responsible Party):
Bristol-Myers Squibb

ClinicalTrials.gov Identifier:
NCT02743494

First received: April 15, 2016
Last updated: October 7, 2016
Last verified: September 2016
History of Changes

Purpose

The purpose of this study is to determine whether nivolumab will improve overall survival, disease-free survival, or both compared with placebo.

Condition	Intervention	Phase
Advanced Cancer	Drug: Nivolumab Other: Placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Randomized, Multicenter, Double Blind, Phase III Study of Adjuvant Nivolumab or Placebo in Subjects With Resected Esophageal, or Gastroesophageal Junction Cancer

Resource links provided by NLM:

MedlinePlus related topics: Cancer

Drug Information available for: Nivolumab

U.S. FDA Resources

Further study details as provided by Bristol-Myers Squibb:

Primary Outcome Measures:

- Disease-Free Survival of adjuvant nivolumab in subjects with resected esophageal cancer or gastroesophageal junction cancer who have received chemoradiotherapy followed by surgery [Time Frame: Approximately 29 months after the first subject is randomized]
  [Designated as safety issue: No]
- Overall Survival of adjuvant nivolumab in subjects with resected esophageal cancer or gastroesophageal junction cancer who have received chemoradiotherapy followed by surgery [Time Frame: Approximately 42 months after the first subject is randomized]
  [Designated as safety issue: No]

Secondary Outcome Measures:

- Overall survival rate [Time Frame: Overall survival rate at 1, 2, and 3 years] [Designated as safety issue: No]

Estimated Enrollment: 760
Study Start Date: May 2016
Estimated Study Completion Date: April 2021
Estimated Primary Completion Date: May 2019 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Nivolumab Specified dose on specified days.	Drug: Nivolumab Specified dose on specified days

Placebo Comparator: Placebo Specified dose on specified days.	Other: Placebo Specified dose on specified days

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Diagnosed with Stage II/III carcinoma of the esophagus or gastroesophageal junction
- Completed pre-operative chemo radiotherapy followed by surgery
- Diagnosed with residual pathologic disease after being surgically rendered free of disease with negative margins following complete resection

Exclusion Criteria:

- Diagnosed with cervical esophageal carcinoma
- Diagnosed with Stage IV resectable disease
- Did not receive concurrent chemoradiotherapy prior to surgery

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02743494

Contacts

Contact: Recruiting sites have contact information. Please contact the sites directly. If there is no contact information, please email: Clinical.Trials@bms.com

Contact: First line of the email MUST contain NCT# and Site #.

Show 147 Study Locations

Sponsors and Collaborators

Bristol-Myers Squibb

Investigators

Study Director: Bristol-Myers Squibb Bristol-Myers Squibb

More Information

Additional Information:

BMS Clinical Trial Information EXIT

BMS clinical trial educational resource EXIT

Investigator Inquiry form EXIT

FDA Safety Alerts and Recalls EXIT

Responsible Party: Bristol-Myers Squibb
ClinicalTrials.gov Identifier: NCT02743494 History of Changes
Other Study ID Numbers: **CA209-577** 2015-005556-10
Study First Received: April 15, 2016
Last Updated: October 7, 2016
Health Authority: Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica
Argentina: Human Research Bioethics Committee
Australia: National Health and Medical Research Council
Belgium: The Federal Public Service (FPS) Health, Food Chain Safety and Environment
Brazil: Ethics Committee
Brazil: Ministry of Health
Brazil: National Committee of Ethics in Research
Brazil: National Health Surveillance Agency
Canada: Canadian Institutes of Health Research
Canada: Ethics Review Committee
Canada: Health Canada
Canada: Ministry of Health & Long Term Care, Ontario
Czech Republic: Ethics Committee
Czech Republic: State Institute for Drug Control
Denmark: Danish Medicines Agency
Denmark: National Board of Health
Denmark: The Danish National Committee on Biomedical Research Ethics
France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)

Hungary: National Institute of Pharmacy
Hungary: Research Ethics Medical Committee
Germany: Federal Institute for Drugs and Medical Devices
Ireland: Irish Medicines Board
Ireland: Medical Ethics Research Committee
Italy: National Monitoring Centre for Clinical Trials - Ministry of Health
Italy: Ministry of Health
Italy: The Italian Medicines Agency
Israel: The Israel National Institute for Health Policy Research and Health Services Research
Mexico: Federal Commission for Protection Against Health Risks
Mexico: National Institute of Public Health, Health Secretariat
Netherlands: The Central Committee on Research Involving Human Subjects (CCMO)
Peru: General Directorate of Pharmaceuticals, Devices, and Drugs
Peru: Instituto Nacional de Salud
Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
Poland: The Central Register of Clinical Trials
Romania: National Authority for Scientific Research
Romania: National Medicines Agency
Romania: State Institute for Drug Control
Russia: FSI Scientific Center of Expertise of Medical Application
Russia: Ministry of Health of the Russian Federation
Spain: Spanish Agency of Medicines
Switzerland: Federal Office of Public Health
Switzerland: Laws and standards
Switzerland: Swissmedic
United Kingdom: Medicines and Healthcare Products Regulatory Agency
United Kingdom: Research Ethics Committee
United States: Institutional Review Board
United States: Food and Drug Administration
United States: Federal Government
Turkey: Ministry of Health
Japan: Pharmaceuticals and Medical Devices Agency
Korea: Ministry of Food and Drug Safety
Taiwan : Food and Drug Administration

Additional relevant MeSH terms:
Nivolumab
Antibodies, Monoclonal
Antineoplastic Agents
Immunologic Factors
Physiological Effects of Drugs

ClinicalTrials.gov processed this record on November 01, 2016