Efficacy, Immunogenicity, and Safety of a Single Dose of V710 in Adult Patients Scheduled for Cardiothoracic Surgery (V710-003 AM2)

This study has been terminated.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00518687

First received: August 17, 2007
Last updated: October 1, 2015
Last verified: October 2015
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

This study will assess the efficacy of a single dose of V710 vaccine to prevent serious Staphylococcus aureus infections following elective cardiothoracic surgery. The study will also evaluate the immune response and general safety of the V710 vaccine.

Condition	Intervention	Phase
Staphylococcus Aureus Bacteremia Mediastinitis	Biological: V710 Biological: Placebo	Phase 2 Phase 3

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

Official Title: A Randomized, Multicenter, Double-Blind, Group-Sequential Study to Evaluate the Efficacy, Immunogenicity, and Safety of a Single Dose of Merck 0657nI Staphylococcus Aureus Vaccine (V710) in Adult Patients Scheduled for Cardiothoracic Surgery

Resource links provided by NLM:

Drug Information available for: Staphylococcus aureus

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

Number of Participants With Staphylococcus Aureus Bacteremia and/or Deep Sternal Wound Infection [Time Frame: Up to 90 days after surgery] [Designated as safety issue: No]

Diagnosis of the Staphylococcus aureus infections employed standardized definitions adapted from the Centers for Disease Control (CDC) Guidelines for Nosocomial infections (Garner JS, Jarvis WS, Emori TG, et al. CDC definitions for nosocomial infections. APIC Infect Control App Epidemiol 1996;A1-20). Bacteremia was defined as ≥1 positive blood culture for S. aureus regardless of the presence of clinical symptoms. A Staphylococcus aureus deep sternal wound infection included mediastinitis or a deep incisional surgical-site infection involving the sternal wound.

- Incidence Rate of Vaccine-related Serious Adverse Experiences [Time Frame: Up to 360 days after surgery] [Designated as safety issue: Yes]

  Vaccine-related adverse experiences were those deemed by the investigator to be possibly, probably, or definitely vaccine related. A serious adverse experience was any adverse experience occurring at any dose that 1) resulted in death, 2) was life threatening, 3) resulted in a persistent or significant disability/incapacity, 4) resulted in or prolonged an existing inpatient hospitalization, 5) was a congenital anomaly/birth defect, 6) was a cancer, 7) was an overdose, or 8) jeopardized the participant and required medical or surgical intervention.

Secondary Outcome Measures:

- Number of Participants With Invasive Staphylococcus Aureus Infection [Time Frame: Up to 90 days after surgery] [Designated as safety issue: No]

  Diagnosis of the Staphylococcus aureus infections employed standardized definitions adapted from the CDC Guidelines for Nosocomial infections. An invasive Staphylococcus infection included bacteremia, deep sternal wound infection, deep-tissue organ/space infection at another surgical site, or any other deep-tissue infection.

- Number of Participants With Surgical-site Staphylococcus Aureus Infection [Time Frame: Up to 90 days after surgery] [Designated as safety issue: No]

  Diagnosis of the Staphylococcus aureus infections employed standardized definitions adapted from the CDC Guidelines for Nosocomial infections. A Staphylococcus infection surgical-site infection included any superficial incisional, deep incisional, or organ/space infection at the sternal site, the vascular harvest (donor) site, or any other site at which the surgery was performed.

Enrollment:	8031
Study Start Date:	December 2007
Study Completion Date:	August 2011
Primary Completion Date:	August 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: V710 60 µg	Biological: V710 0.5-mL single injection of V710 (60 µg) Other Name: Merck 0657nI Staphylococcus aureus vaccine
Placebo Comparator: Placebo	Biological: Placebo 0.5-mL single injection of matching placebo

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Participant is scheduled to undergo cardiothoracic surgery involving a full median sternotomy (not including cardiac transplantation surgery) within 14 to 60 days after vaccination.
- Female participants of reproductive potential are required to have a negative urine or serum pregnancy test immediately prior to study vaccination and must use an acceptable form of birth control.

Exclusion Criteria:

- Participants had an invasive Staphylococcus aureus infection within the past 3 months prior to study entry.
- A realistic (>50%) possibility that cardiothoracic surgery will be necessary sooner than 10 days after vaccination.
- Participant is planning to undergo cardiac transplantation surgery or sternal debridement to remedy an infection resulting from a prior cardiothoracic surgery.
- Participant has any type of ventricular-assist device in place at the time of study entry.
- Participant has a history of anaphylaxis to any of the vaccine components.
- Participant received V710 vaccine, any other investigational Staphylococcus aureus vaccine, or investigational Staphylococcus aureus antibodies.
- Participant has a temperature of ≥100.4ºF (≥38.0ºC), oral equivalent, within 48 hours prior to study vaccination.
- Participant has impairment of the immune system.
- Participant has a medical condition in which the expected survival is less than 90 days.

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.

No Contacts or Locations Provided

More Information

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Fowler VG, Allen KB, Moreira ED, Moustafa M, Isgro F, Boucher HW, Corey GR, Carmeli Y, Betts R, Hartzel JS, Chan IS, McNeely TB, Kartsonis NA, Guris D, Onorato MT, Smugar SS, DiNubile MJ, Sobanjo-ter Meulen A. Effect of an investigational vaccine for preventing Staphylococcus aureus infections after cardiothoracic surgery: a randomized trial. JAMA. 2013 Apr 3;309(13):1368-78. doi: 10.1001/jama.2013.3010.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00518687 History of Changes
Other Study ID Numbers:	V710-003 2007_523
Study First Received:	August 17, 2007
Results First Received:	October 2, 2012
Last Updated:	October 1, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

- Bacteremia
- Mediastinitis
- Bacterial Infections
- Infection
- Inflammation
- Mediastinal Diseases
- Pathologic Processes
- Respiratory Tract Diseases
- Sepsis
- Systemic Inflammatory Response Syndrome
- Thoracic Diseases

ClinicalTrials.gov processed this record on April 20, 2016

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK

Efficacy, Immunogenicity, and Safety of a Single Dose of V710 in Adult Patients Scheduled for Cardiothoracic Surgery (V710-003 AM2)

This study has been terminated.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00518687

First received: August 17, 2007
Last updated: October 1, 2015
Last verified: October 2015
History of Changes

Results First Received: October 2, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Prevention
Conditions:	Staphylococcus Aureus Bacteremia Mediastinitis
Interventions:	Biological: V710 Biological: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
V710 60 µg	V710: 0.5-ml single injection of V710 (60 µg)
Placebo	Placebo : 0.5-ml single injection of matching placebo

Participant Flow: Overall Study

	V710 60 µg	Placebo
STARTED	**4005** [1]	**4005** [2]
Vaccinated	**3981**	**3982**
COMPLETED	**2568**	**2585**
NOT COMPLETED	**1437**	**1420**
Adverse Event	**201**	**177**
Lost to Follow-up	**144**	**155**
Physician Decision	**42**	**48**
Progressive disease	**2**	**2**
Protocol Violation	**8**	**10**
Study terminated by sponsor	**930**	**918**
Withdrawal by Subject	**110**	**110**

[1] An additional 10 participants were not analyzed because of questionable clinical practices at 1 site
[2] An additional 11 participants were not analyzed because of questionable clinical practices at 1 site

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
V710 60 µg	V710: 0.5-ml single injection of V710 (60 µg)
Placebo	Placebo : 0.5-ml single injection of matching placebo
Total	Total of all reporting groups

Baseline Measures

	V710 60 µg	Placebo	Total
Number of Participants [units: participants]	4005	4005	8010
Age [units: years] Mean (Standard Deviation)	63.6 (12.6)	63.9 (12.5)	63.8 (12.5)
Gender [units: participants]			
Female	1328	1336	2664
Male	2677	2669	5346

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With Staphylococcus Aureus Bacteremia and/or Deep Sternal Wound Infection [Time Frame: Up to 90 days after surgery]

Measure Type	Primary
Measure Title	Number of Participants With Staphylococcus Aureus Bacteremia and/or Deep Sternal Wound Infection
Measure Description	Diagnosis of the Staphylococcus aureus infections employed standardized definitions adapted from the Centers for Disease Control (CDC) Guidelines for Nosocomial infections (Garner JS, Jarvis WS, Emori TG, et al. CDC definitions for nosocomial infections. APIC Infect Control App Epidemiol 1996;A1-20). Bacteremia was defined as ≥1 positive blood culture for S. aureus regardless of the presence of clinical symptoms. A Staphylococcus aureus deep sternal wound infection included mediastinitis or a deep incisional surgical-site infection involving the sternal wound.
Time Frame	Up to 90 days after surgery
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population analyzed was the full analysis set: participants who were vaccinated and subsequently underwent cardiothoracic surgery involving full median sternotomy at least 14 days and at most 60 days after vaccination

Reporting Groups

	Description
V710 60 µg	V710: 0.5-ml single injection of V710 (60 µg)
Placebo	Placebo : 0.5-ml single injection of matching placebo

Measured Values

	V710 60 µg	Placebo
Number of Participants Analyzed [units: participants]	3528	3517
Number of Participants With Staphylococcus Aureus Bacteremia and/or Deep Sternal Wound Infection		

[units: participants]	**22**	**27**

Statistical Analysis 1 for Number of Participants With Staphylococcus Aureus Bacteremia and/or Deep Sternal Wound Infection

Groups [1]	All groups
Method [2]	Exact 1-sided binomial test
P Value [3]	0.584
Vaccine Efficacy (VE) [4]	18.5
95% Confidence Interval	-48.6 to 55.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	A 1-sided p-value <0.025 implies that the V710 vaccine efficacy is statistically significantly greater than 20%
[4]	Other relevant estimation information:
	VE = 1 - Relative Risk of V710 compared with placebo

2. Primary: Incidence Rate of Vaccine-related Serious Adverse Experiences [Time Frame: Up to 360 days after surgery]

Measure Type	Primary
Measure Title	Incidence Rate of Vaccine-related Serious Adverse Experiences
Measure Description	Vaccine-related adverse experiences were those deemed by the investigator to be possibly, probably, or definitely vaccine related. A serious adverse experience was any adverse experience occurring at any dose that 1) resulted in death, 2) was life threatening, 3) resulted in a persistent or significant disability/incapacity, 4) resulted in or prolonged an existing inpatient hospitalization, 5) was a congenital anomaly/birth defect, 6) was a cancer, 7) was an overdose, or 8) jeopardized the participant and required medical or surgical intervention.
Time Frame	Up to 360 days after surgery
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population analyzed included all vaccinated participants with follow-up results

Reporting Groups

	Description
V710 60 µg	V710: 0.5-ml single injection of V710 (60 µg)
Placebo	Placebo : 0.5-ml single injection of matching

	placebo

Measured Values

	V710 60 µg	Placebo
Number of Participants Analyzed [units: participants]	**3958**	**3967**
Incidence Rate of Vaccine-related Serious Adverse Experiences [units: Events per 100 person-years]	**0.0**	**0.0**

Statistical Analysis 1 for Incidence Rate of Vaccine-related Serious Adverse Experiences

Groups [1]	All groups
Method [2]	Miettinen and Nurminen
P Value [3]	0.997
Estimated rate difference [4]	0.0
95% Confidence Interval	-0.1 to 0.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

3. Secondary: Number of Participants With Invasive Staphylococcus Aureus Infection [Time Frame: Up to 90 days after surgery]

Measure Type	Secondary
Measure Title	Number of Participants With Invasive Staphylococcus Aureus Infection
Measure Description	Diagnosis of the Staphylococcus aureus infections employed standardized definitions adapted from the CDC Guidelines for Nosocomial infections. An invasive Staphylococcus infection included bacteremia, deep sternal wound infection, deep-tissue organ/space infection at another surgical site, or any other deep-tissue infection.
Time Frame	Up to 90 days after surgery
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

The population analyzed was the full analysis set: participants who were vaccinated and subsequently underwent cardiothoracic surgery involving full median sternotomy at least 14 days and at most 60 days after vaccination

Reporting Groups

	Description
V710 60 µg	V710: 0.5-ml single injection of V710 (60 µg)
Placebo	Placebo : 0.5-ml single injection of matching placebo

Measured Values

	V710 60 µg	Placebo
Number of Participants Analyzed [units: participants]	**3528**	**3517**
Number of Participants With Invasive Staphylococcus Aureus Infection [units: participants]	**27**	**31**

Statistical Analysis 1 for Number of Participants With Invasive Staphylococcus Aureus Infection

Groups [1]	All groups
Method [2]	Exact 1-sided binomial test
P Value [3]	0.347
Vaccine Efficacy (VE) [4]	12.9
95% Confidence Interval	-50.8 to 50.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	A 1-sided p-value <0.025 implies that the V710 vaccine efficacy is statistically significant
[4]	Other relevant estimation information:
	VE = 1 - Relative Risk of V710 compared with placebo

4. Secondary: Number of Participants With Surgical-site Staphylococcus Aureus Infection [Time Frame: Up to 90 days after surgery]

Measure Type	Secondary
Measure Title	Number of Participants With Surgical-site Staphylococcus Aureus Infection
Measure Description	Diagnosis of the Staphylococcus aureus infections employed standardized definitions adapted from the CDC Guidelines for Nosocomial infections. A Staphylococcus infection surgical-site infection included any superficial incisional, deep incisional, or organ/space infection at the sternal site, the vascular harvest (donor) site, or any other site at which the

	surgery was performed.
Time Frame	Up to 90 days after surgery
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population analyzed was the full analysis set: participants who were vaccinated and subsequently underwent cardiothoracic surgery involving full median sternotomy at least 14 days and at most 60 days after vaccination

Reporting Groups

	Description
V710 60 µg	V710: 0.5-ml single injection of V710 (60 µg)
Placebo	Placebo : 0.5-ml single injection of matching placebo

Measured Values

	V710 60 µg	**Placebo**
Number of Participants Analyzed [units: participants]	**3528**	**3517**
Number of Participants With Surgical-site Staphylococcus Aureus Infection [units: participants]	**53**	**75**

Statistical Analysis 1 for Number of Participants With Surgical-site Staphylococcus Aureus Infection

Groups [1]	All groups
Method [2]	Exact 1-sided binomial test
P Value [3]	0.032
Vaccine Efficacy (VE) [4]	29.3
95% Confidence Interval	-1.8 to 51.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	A 1-sided p-value <0.025 implies that the V710 vaccine efficacy is statistically significant
[4]	Other relevant estimation information:
	VE = 1 - Relative Risk of V710 compared with placebo

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	All serious adverse events (SAEs): through Day 14 after vaccination; vaccine-related SAEs, SAEs resulting in death, and SAEs involving infection diagnosis: through Day 360 after surgery; other adverse events (AEs): through Day 14 after vaccination
Additional Description	The population analyzed was all vaccinated participants with follow-up results

Reporting Groups

	Description
V710 (60 µg) Lyophilized	V710: 0.5-ml single injection of V710 (60 µg)
Placebo	Placebo : 0.5-ml single injection of matching placebo

Serious Adverse Events

	V710 (60 µg) Lyophilized	Placebo
Total, serious adverse events		
# participants affected / at risk	**291/3958 (7.35%)**	**274/3967 (6.91%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**3/3958 (0.08%)**	**3/3967 (0.08%)**
# events	**3**	**3**
Febrile neutropenia † 1		
# participants affected / at risk	**1/3958 (0.03%)**	**0/3967 (0.00%)**
# events	**1**	**0**
Microcytic anaemia † 1		
# participants affected / at risk	**0/3958 (0.00%)**	**1/3967 (0.03%)**
# events	**0**	**1**
Pancytopenia † 1		
# participants affected / at risk	**0/3958 (0.00%)**	**1/3967 (0.03%)**
# events	**0**	**1**
Cardiac disorders		
Acute coronary syndrome † 1		
# participants affected / at risk	**1/3958 (0.03%)**	**0/3967 (0.00%)**
# events	**1**	**0**
Acute myocardial infarction † 1		
# participants affected / at risk	**6/3958 (0.15%)**	**11/3967 (0.28%)**
# events	**6**	**11**
Angina pectoris † 1		
# participants affected / at risk	**3/3958 (0.08%)**	**1/3967 (0.03%)**
# events	**3**	**1**
Angina unstable † 1		

# participants affected / at risk	4/3958 (0.10%)	1/3967 (0.03%)
# events	4	1
Arrhythmia † 1		
# participants affected / at risk	1/3958 (0.03%)	2/3967 (0.05%)
# events	1	2
Atrial fibrillation † 1		
# participants affected / at risk	4/3958 (0.10%)	1/3967 (0.03%)
# events	4	1
Atrioventricular block second degree † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Cardiac arrest † 1		
# participants affected / at risk	18/3958 (0.45%)	21/3967 (0.53%)
# events	18	21
Cardiac failure † 1		
# participants affected / at risk	12/3958 (0.30%)	6/3967 (0.15%)
# events	12	6
Cardiac failure acute † 1		
# participants affected / at risk	2/3958 (0.05%)	0/3967 (0.00%)
# events	2	0
Cardiac failure chronic † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Cardiac failure congestive † 1		
# participants affected / at risk	5/3958 (0.13%)	5/3967 (0.13%)
# events	5	5
Cardiac tamponade † 1		
# participants affected / at risk	1/3958 (0.03%)	2/3967 (0.05%)
# events	1	2
Cardiac valve disease † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Cardiac ventricular disorder † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Cardio-respiratory arrest † 1		
# participants affected / at risk	8/3958 (0.20%)	2/3967 (0.05%)
# events	8	2
Cardiogenic shock † 1		
# participants affected / at risk	23/3958 (0.58%)	18/3967 (0.45%)
# events	23	18
Cardiopulmonary failure † 1		
# participants affected / at risk	1/3958 (0.03%)	1/3967 (0.03%)
# events	1	1
Coronary artery disease † 1		

# participants affected / at risk	2/3958 (0.05%)	1/3967 (0.03%)
# events	2	1
Ischaemic cardiomyopathy † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Left ventricular dysfunction † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Left ventricular failure † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Low cardiac output syndrome † 1		
# participants affected / at risk	2/3958 (0.05%)	1/3967 (0.03%)
# events	2	1
Myocardial infarction † 1		
# participants affected / at risk	3/3958 (0.08%)	8/3967 (0.20%)
# events	3	8
Pericardial haemorrhage † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Right ventricular failure † 1		
# participants affected / at risk	2/3958 (0.05%)	5/3967 (0.13%)
# events	2	5
Sinus arrest † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Ventricle rupture † 1		
# participants affected / at risk	2/3958 (0.05%)	0/3967 (0.00%)
# events	2	0
Ventricular arrhythmia † 1		
# participants affected / at risk	1/3958 (0.03%)	1/3967 (0.03%)
# events	1	1
Ventricular dysfunction † 1		
# participants affected / at risk	2/3958 (0.05%)	0/3967 (0.00%)
# events	2	0
Ventricular failure † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Ventricular fibrillation † 1		
# participants affected / at risk	3/3958 (0.08%)	1/3967 (0.03%)
# events	4	1
Ventricular tachyarrhythmia † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Ventricular tachycardia † 1		
# participants affected / at risk	1/3958 (0.03%)	1/3967 (0.03%)

# events	1	1
Congenital, familial and genetic disorders		
Cerebral arteriovenous malformation haemorrhagic † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Eye disorders		
Blindness † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Gastrointestinal disorders		
Anal haemorrhage † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Diarrhoea † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Diverticular perforation † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Duodenal ulcer haemorrhage † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Gastric ulcer † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Gastrointestinal haemorrhage † 1		
# participants affected / at risk	3/3958 (0.08%)	3/3967 (0.08%)
# events	3	3
Intestinal infarction † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Intestinal ischaemia † 1		
# participants affected / at risk	1/3958 (0.03%)	2/3967 (0.05%)
# events	1	2
General disorders		
Chest pain † 1		
# participants affected / at risk	3/3958 (0.08%)	2/3967 (0.05%)
# events	3	2
Death † 1		
# participants affected / at risk	3/3958 (0.08%)	4/3967 (0.10%)
# events	3	4
Device dislocation † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0

Device leakage † 1		
# participants affected / at risk	**1/3958 (0.03%)**	**0/3967 (0.00%)**
# events	**1**	**0**
Multi-organ failure † 1		
# participants affected / at risk	**31/3958 (0.78%)**	**17/3967 (0.43%)**
# events	**31**	**17**
Organ failure † 1		
# participants affected / at risk	**0/3958 (0.00%)**	**1/3967 (0.03%)**
# events	**0**	**1**
Sudden cardiac death † 1		
# participants affected / at risk	**3/3958 (0.08%)**	**2/3967 (0.05%)**
# events	**3**	**2**
Sudden death † 1		
# participants affected / at risk	**3/3958 (0.08%)**	**2/3967 (0.05%)**
# events	**3**	**2**
Systemic inflammatory response syndrome † 1		
# participants affected / at risk	**1/3958 (0.03%)**	**0/3967 (0.00%)**
# events	**1**	**0**
Hepatobiliary disorders		
Cholelithiasis † 1		
# participants affected / at risk	**1/3958 (0.03%)**	**0/3967 (0.00%)**
# events	**1**	**0**
Cytolytic hepatitis † 1		
# participants affected / at risk	**0/3958 (0.00%)**	**1/3967 (0.03%)**
# events	**0**	**1**
Hepatic failure † 1		
# participants affected / at risk	**0/3958 (0.00%)**	**1/3967 (0.03%)**
# events	**0**	**1**
Infections and infestations		
Bacteraemia † 1		
# participants affected / at risk	**1/3958 (0.03%)**	**0/3967 (0.00%)**
# events	**1**	**0**
Campylobacter gastroenteritis † 1		
# participants affected / at risk	**0/3958 (0.00%)**	**1/3967 (0.03%)**
# events	**0**	**1**
Candida sepsis † 1		
# participants affected / at risk	**0/3958 (0.00%)**	**1/3967 (0.03%)**
# events	**0**	**1**
Cellulitis staphylococcal † 1		
# participants affected / at risk	**0/3958 (0.00%)**	**1/3967 (0.03%)**
# events	**0**	**1**
Clostridium difficile colitis † 1		
# participants affected / at risk	**1/3958 (0.03%)**	**0/3967 (0.00%)**
# events	**1**	**0**
Diarrhoea infectious † 1		

# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Endocarditis † 1		
# participants affected / at risk	1/3958 (0.03%)	2/3967 (0.05%)
# events	1	2
Endocarditis pseudomonal † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Endocarditis staphylococcal † 1		
# participants affected / at risk	2/3958 (0.05%)	4/3967 (0.10%)
# events	2	4
Enterococcal sepsis † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Fungal endocarditis † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Klebsiella infection † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Mediastinitis † 1		
# participants affected / at risk	3/3958 (0.08%)	1/3967 (0.03%)
# events	3	1
Pneumonia † 1		
# participants affected / at risk	5/3958 (0.13%)	6/3967 (0.15%)
# events	5	6
Pneumonia bacterial † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Pneumonia staphylococcal † 1		
# participants affected / at risk	4/3958 (0.10%)	8/3967 (0.20%)
# events	4	9
Postoperative wound infection † 1		
# participants affected / at risk	2/3958 (0.05%)	1/3967 (0.03%)
# events	2	1
Prostatic abscess † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Pulmonary sepsis † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Pyonephrosis † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Respiratory tract infection † 1		
# participants affected / at risk	1/3958 (0.03%)	1/3967 (0.03%)

# events	1	1
Sepsis † 1		
# participants affected / at risk	3/3958 (0.08%)	2/3967 (0.05%)
# events	3	2
Septic shock † 1		
# participants affected / at risk	7/3958 (0.18%)	5/3967 (0.13%)
# events	7	5
Skin infection † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Staphylococcal abscess † 1		
# participants affected / at risk	1/3958 (0.03%)	2/3967 (0.05%)
# events	1	2
Staphylococcal bacteraemia † 1		
# participants affected / at risk	18/3958 (0.45%)	19/3967 (0.48%)
# events	18	19
Staphylococcal infection † 1		
# participants affected / at risk	5/3958 (0.13%)	5/3967 (0.13%)
# events	5	5
Staphylococcal mediastinitis † 1		
# participants affected / at risk	8/3958 (0.20%)	9/3967 (0.23%)
# events	8	9
Staphylococcal osteomyelitis † 1		
# participants affected / at risk	1/3958 (0.03%)	1/3967 (0.03%)
# events	1	1
Staphylococcal sepsis † 1		
# participants affected / at risk	3/3958 (0.08%)	2/3967 (0.05%)
# events	3	2
Staphylococcal skin infection † 1		
# participants affected / at risk	0/3958 (0.00%)	2/3967 (0.05%)
# events	0	2
Streptococcal sepsis † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Tracheobronchitis † 1		
# participants affected / at risk	4/3958 (0.10%)	1/3967 (0.03%)
# events	4	1
Urosepsis † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Wound infection † 1		
# participants affected / at risk	2/3958 (0.05%)	0/3967 (0.00%)
# events	2	0
Wound infection bacterial † 1		
# participants affected / at risk	2/3958 (0.05%)	0/3967 (0.00%)

# events	2	0
Wound infection staphylococcal † 1		
# participants affected / at risk	25/3958 (0.63%)	27/3967 (0.68%)
# events	25	28
Injury, poisoning and procedural complications		
Abdominal injury † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Anastomotic ulcer † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Brain herniation † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Cardiac valve replacement complication † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Contusion † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Hip fracture † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Intraoperative cerebral artery occlusion † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Operative haemorrhage † 1		
# participants affected / at risk	3/3958 (0.08%)	0/3967 (0.00%)
# events	3	0
Post procedural haemorrhage † 1		
# participants affected / at risk	1/3958 (0.03%)	2/3967 (0.05%)
# events	1	2
Postoperative thoracic procedure complication † 1		
# participants affected / at risk	2/3958 (0.05%)	0/3967 (0.00%)
# events	2	0
Postoperative wound complication † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Rib fracture † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Subdural haematoma † 1		
# participants affected / at risk	1/3958 (0.03%)	1/3967 (0.03%)
# events	1	1
Vasoplegia syndrome † 1		

# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Investigations		
Blood creatinine increased † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Cardiac output decreased † 1		
# participants affected / at risk	1/3958 (0.03%)	1/3967 (0.03%)
# events	1	1
Troponin T increased † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Metabolism and nutrition disorders		
Diabetes mellitus † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Metabolic acidosis † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Musculoskeletal and connective tissue disorders		
Bone fistula † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Acute myeloid leukaemia † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Brain neoplasm † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Bronchial carcinoma † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Chronic lymphocytic leukaemia † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Colon cancer † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Gastric cancer † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Lymphoma † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)

# events	0	1
Metastatic renal cell carcinoma † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Multiple myeloma † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Neoplasm malignant † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Pancreatic carcinoma † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Rectal cancer † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Renal neoplasm † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Thyroid cancer † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Nervous system disorders		
Basal ganglia infarction † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Brain stem haemorrhage † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Brain stem infarction † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Carotid artery stenosis † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Cerebral disorder † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Cerebral haemorrhage † 1		
# participants affected / at risk	2/3958 (0.05%)	2/3967 (0.05%)
# events	2	2
Cerebral infarction † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Cerebral ischaemia † 1		

# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Cerebrovascular accident † 1		
# participants affected / at risk	2/3958 (0.05%)	3/3967 (0.08%)
# events	2	3
Dizziness exertional † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Encephalitis † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Haemorrhage intracranial † 1		
# participants affected / at risk	1/3958 (0.03%)	1/3967 (0.03%)
# events	1	1
Haemorrhagic stroke † 1		
# participants affected / at risk	1/3958 (0.03%)	1/3967 (0.03%)
# events	1	1
Hypoxic-ischaemic encephalopathy † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Intraventricular haemorrhage † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Ischaemic stroke † 1		
# participants affected / at risk	1/3958 (0.03%)	2/3967 (0.05%)
# events	1	2
Loss of consciousness † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Presyncope † 1		
# participants affected / at risk	0/3958 (0.00%)	2/3967 (0.05%)
# events	0	2
Syncope † 1		
# participants affected / at risk	2/3958 (0.05%)	3/3967 (0.08%)
# events	2	3
Transient ischaemic attack † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Psychiatric disorders		
Panic attack † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Renal and urinary disorders		
Renal failure † 1		
# participants affected / at risk	0/3958 (0.00%)	3/3967 (0.08%)

# events	0	3
Renal failure acute † 1		
# participants affected / at risk	4/3958 (0.10%)	2/3967 (0.05%)
# events	4	2
Renal failure chronic † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Reproductive system and breast disorders		
Epididymitis † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Respiratory, thoracic and mediastinal disorders		
Acute respiratory distress syndrome † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Acute respiratory failure † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Dyspnoea † 1		
# participants affected / at risk	3/3958 (0.08%)	0/3967 (0.00%)
# events	3	0
Hydropneumothorax † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Pneumonia aspiration † 1		
# participants affected / at risk	1/3958 (0.03%)	2/3967 (0.05%)
# events	1	2
Pulmonary congestion † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Pulmonary embolism † 1		
# participants affected / at risk	3/3958 (0.08%)	1/3967 (0.03%)
# events	3	1
Pulmonary fibrosis † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Pulmonary mass † 1		
# participants affected / at risk	1/3958 (0.03%)	0/3967 (0.00%)
# events	1	0
Pulmonary oedema † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1

Respiratory arrest † 1		
# participants affected / at risk	**1/3958 (0.03%)**	**0/3967 (0.00%)**
# events	**1**	**0**
Respiratory failure † 1		
# participants affected / at risk	**8/3958 (0.20%)**	**6/3967 (0.15%)**
# events	**8**	**6**
Vascular disorders		
Aneurysm ruptured † 1		
# participants affected / at risk	**1/3958 (0.03%)**	**0/3967 (0.00%)**
# events	**1**	**0**
Aortic aneurysm † 1		
# participants affected / at risk	**0/3958 (0.00%)**	**1/3967 (0.03%)**
# events	**0**	**1**
Aortic aneurysm rupture † 1		
# participants affected / at risk	**0/3958 (0.00%)**	**1/3967 (0.03%)**
# events	**0**	**1**
Aortic dissection † 1		
# participants affected / at risk	**0/3958 (0.00%)**	**1/3967 (0.03%)**
# events	**0**	**1**
Aortic rupture † 1		
# participants affected / at risk	**1/3958 (0.03%)**	**1/3967 (0.03%)**
# events	**1**	**1**
Aortic stenosis † 1		
# participants affected / at risk	**2/3958 (0.05%)**	**0/3967 (0.00%)**
# events	**2**	**0**
Arterial thrombosis † 1		
# participants affected / at risk	**0/3958 (0.00%)**	**1/3967 (0.03%)**
# events	**0**	**1**
Arteriosclerosis obliterans † 1		
# participants affected / at risk	**1/3958 (0.03%)**	**0/3967 (0.00%)**
# events	**1**	**0**
Circulatory collapse † 1		
# participants affected / at risk	**3/3958 (0.08%)**	**9/3967 (0.23%)**
# events	**3**	**9**
Deep vein thrombosis † 1		
# participants affected / at risk	**1/3958 (0.03%)**	**0/3967 (0.00%)**
# events	**1**	**0**
Embolism † 1		
# participants affected / at risk	**0/3958 (0.00%)**	**1/3967 (0.03%)**
# events	**0**	**1**
Haemorrhage † 1		
# participants affected / at risk	**3/3958 (0.08%)**	**2/3967 (0.05%)**
# events	**3**	**2**
Hypertensive crisis † 1		
# participants affected / at risk	**1/3958 (0.03%)**	**0/3967 (0.00%)**

# events	1	0
Hypovolaemic shock † 1		
# participants affected / at risk	1/3958 (0.03%)	4/3967 (0.10%)
# events	1	4
Shock † 1		
# participants affected / at risk	0/3958 (0.00%)	1/3967 (0.03%)
# events	0	1
Shock haemorrhagic † 1		
# participants affected / at risk	1/3958 (0.03%)	3/3967 (0.08%)
# events	1	3

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	All serious adverse events (SAEs): through Day 14 after vaccination; vaccine-related SAEs, SAEs resulting in death, and SAEs involving infection diagnosis: through Day 360 after surgery; other adverse events (AEs): through Day 14 after vaccination
Additional Description	The population analyzed was all vaccinated participants with follow-up results

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
V710 (60 µg) Lyophilized	V710: 0.5-ml single injection of V710 (60 µg)
Placebo	Placebo : 0.5-ml single injection of matching placebo

Other Adverse Events

	V710 (60 µg) Lyophilized	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	749/3958 (18.92%)	343/3967 (8.65%)
General disorders		
Injection site erythema † 1		
# participants affected / at risk	280/3958 (7.07%)	102/3967 (2.57%)
# events	285	104
Injection site pain † 1		
# participants affected / at risk	533/3958 (13.47%)	232/3967 (5.85%)
# events	575	244
† 1		

Injection site swelling		
# participants affected / at risk	**217/3958 (5.48%)**	**79/3967 (1.99%)**
# events	**222**	**79**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: The sponsor must have the opportunity to review all proposed abstracts, manuscripts, or presentations regarding this study 60 days prior to submission for publication/presentation. Any information identified by the sponsor as confidential must be deleted prior to submission.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372
e-mail: ClinicalTrialsDisclosure@merck.com

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Fowler VG, Allen KB, Moreira ED, Moustafa M, Isgro F, Boucher HW, Corey GR, Carmeli Y, Betts R, Hartzel JS, Chan IS, McNeely TB, Kartsonis NA, Guris D, Onorato MT, Smugar SS, DiNubile MJ, Sobanjo-ter Meulen A. Effect of an investigational vaccine for preventing Staphylococcus aureus infections after cardiothoracic surgery: a randomized trial. JAMA. 2013 Apr 3;309(13):1368-78. doi: 10.1001/jama.2013.3010.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00518687 History of Changes
Other Study ID Numbers: V710-003
2007_523 (Other Identifier: Merck)

Study First Received:	August 17, 2007
Results First Received:	October 2, 2012
Last Updated:	October 1, 2015
Health Authority:	United States: Food and Drug Administration

TO TOP

For Patients and Families | **For Researchers** | **For Study Record Managers**

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK