Advanced understanding of Staphylococcus aureus infections in Europe - Surgical Site infections

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON47402

Source
ToetsingOnline

Brief title
ASPIRE-SSI

Condition

- Bacterial infectious disorders

Synonym
Surgical Site Infections

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Europese subsidie. Innovatives Medicine Initiative (IMI) grant no. 115523

Intervention

Keyword: Staphylococcus aureus, Surgical site infections

Outcome measures

Primary outcome

To assess the incidence of S. aureus SSI up to 90 days following surgery and its independent association with patient-related, pathogen-related and contextual factors.

Secondary outcome

*To develop a robust S. aureus SSI and bloodstream infection (BSI) prediction tool for future clinical trials and public health interventions.

*To assess the incidence of serious S. aureus SSI up to 90 days following surgery and its independent association with patient-related, pathogen-related and contextual factors.

*To assess the incidence of S. aureus BSI up to 90 days following surgery and its independent association with patient-related, pathogen-related and contextual factors.

*To assess the incidence of all-cause SSI up to 90 days following surgery.

*To assess the incidence of S. aureus SSI stratified by antibiotic susceptibility up to 90 days following surgery.

*To compare the prevalence of preoperative S. aureus colonization in the nose, throat and perineal region.

*To characterize S. aureus isolates involved in colonization and infection and explore the role of anti-Staphylococcal antibodies as potential biomarkers for

S. aureus SSI and/or serious S. aureus infection.

Study description

Background summary

Surgical site infections (SSIs) are healthcare-associated infections that occur frequently and cause considerable morbidity, mortality and healthcare costs. An important causative pathogen of a SSI is Staphylococcus aureus. The epidemiology of S. aureus SSI has not been fully described, but is urgently needed to support the development of preventive interventions against S. aureus SSIs.

Study objective

The aim of this study is to identify patient related, pathogen related, and contextual factors involved in S. aureus infections, especially S. aureus SSI, in the current surgical patient population in Europe, to identify patient groups with an increased risk on developing these infections, and the prevalence of preoperative S. aureus colonization in nose, throat, and perineal region.

Study design

A prospective, observational, multicenter cohort study that will be conducted in sites distributed across the 4 European sub-regions.

Study burden and risks

Risks associated with participation are minimal since the study procedures necessary for participation are considered relatively safe (e.g. nose swab or venous puncture). The burden of participation in this study is thus considered to be minimal for the same reasons.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. The subject is 18 years of age or older.
2. The subject is undergoing 1 or more of the 10 surgical procedures listed in this protocol. The surgical procedure is planned or unplanned.
3. The subject has been screened for S. aureus colonization from three body regions: nose, throat, and perineum within 30 days prior to surgery, and based on the preoperative S. aureus colonization status of the subject, the subject qualifies for enrolment in the study cohort.
4. Written informed consent has been obtained from the subject prior to enrollment in the study cohort.

Exclusion criteria

1. Parallel participation in any experimental study of an anti-Staphylococcus preventive intervention.
2. An active diagnosis of a SSI as the reason for surgery.
3. Not able to comply with study procedures and follow-up based on Investigator judgment.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-12-2016
Enrollment:	900
Type:	Actual

Ethics review

Approved WMO Date:	05-10-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-11-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-12-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-02-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	

Date:	18-05-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-12-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	31-10-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-01-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02935244
CCMO	NL57595.041.16