Multi-Center Clinical Performance Evaluation of a Rapid In Vitro Diagnostic Device for Direct Detection of Staphylococcus aureus Nasal Colonization: Comparitive Analysis to Culture Screening Method.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Therapeutic procedures and supportive care NEC
Study type	Observational non invasive

Summary

ID

NL-OMON30337

Source
ToetsingOnline

Brief title
Rapid in vitro Detection of S. aureus Nasal Colonization

Condition

- Therapeutic procedures and supportive care NEC

Synonym
pre-operative patients undergoing non-emergent surgery; patients who get a planned operation

Research involving
Human

Sponsors and support

Primary sponsor: 3M Health Care
Source(s) of monetary or material Support: bedrijf 3M

Intervention

Keyword: diagnostic device, nasal colonization, screening, Staphylococcus aureus

Outcome measures

Primary outcome

This is a multi-center prospective, controlled, randomized, blinded clinical study to be conducted in the United States and the European Union.

Clinical Sensitivity: Percent tested positive (positive test results) in a population of affected subjects with the specified agent / disease (i.e. How often the test is positive in subjects colonized with Staphylococcus aureus nasal carriage). Percent clinical sensitivity will be expressed mathematically as:
Number of true-positive results / (Number of true-positive + false-negative results) X 100.

Clinical Specificity: Percent tested negative (negative test results) in a population of subjects without the specified agent / disease (i.e. How often the test is negative in subjects not colonized with Staphylococcus aureus nasal colonization). Percent clinical specificity will be expressed mathematically as:
Number of true-negative results / (Number of true-negative + false-positive

results) X 100.

Predictive Values: Probability that a positive result (positive predictive value, or PPV) accurately indicates the presence of a specific agent or disease or a negative result (negative predictive value, or NPV) accurately indicates the absence of a specific agent or disease.

Percent positive predictive value will be expressed mathematically as:

Number of true-positive results / (Number of true-positive + false-positive results) X 100.

Percent negative predictive value will be expressed mathematically as:

Number of true-negative results / (Number of true-negative + false-negative results) X 100.

Secondary outcome

The precence of S. aureus using traditional sreening method and the precence of MRSA.

Study description

Background summary

The Centers for Disease Control and Prevention (CDC) defines Staphylococcus aureus as a common bacterium found on the skin and in the nose of some people (1). The nares have been defined as the most consistent area in which asymptomatic colonization of Staphylococcus aureus can be found and accounts for approximately 25% - 30% of the population (1, 2, 3). Different colonization patterns such as Persistent Carriers (almost always carry), Intermittent Carriers and Non- Carriers (almost never carry) may play a key role in defining the epidemiology and pathogenesis of infection (2). Staphylococcus aureus is

considered to be an important nasal pathogen that accounts for approximately 20% of surgical-site infections (3, 4, 5, 22, 23). Over the past 50 years the treatment of infections with antibiotics have proven more difficult as resistance of Staphylococcus aureus (Methicillin Resistant Staphylococcus aureus: MRSA) has increased with the more commonly used penicillin-related antibiotics (1). In addition to Staphylococcus aureus, other Staphylococcus species, such as the Coagulase-Negative Staphylococci (CoNS) are increasingly important nasal colonizers that have been isolated in the clinical laboratories.

The CoNS account for about 20 different species and are often considered a single group that are also associated with hospital infections and multi-drug resistance. Data from the National Nosocomial Infections Surveillance System, 1986-1996 (NNIS), prioritized a panel of pathogens isolated from surgical site infections. The most common pathogens included were: Staphylococcus aureus, Coagulase-Negative Staphylococci (CoNS), Enterococcus spp., Escherichia coli, Pseudomonas aeruginosa and Enterobacter spp., (6). Nasal carriers of potential surgical site infection pathogens, such as Staphylococcus aureus are leading to the development of new to the market rapid detection devices for screening subjects.

Study objective

The purpose of the study is to collect nasal swabs to establish clinical performance data of the 3M SA Detector, which will be included in the device instructions for use, claims and support regulatory submissions and design validation requirements applicable to quality systems.

The objective of the study is to establish the 3M SA Detector clinical test performance characteristics of sensitivity, specificity and predictive values for direct detection of Staphylococcus aureus nasal colonization against clinical microbiology laboratory culture methods.

Study design

Sampling:
The clinical sampling is non-blinded and non-randomized. The SAD devices will be packaged in bulk. Study personnel will mark the tubes with the subject number and the order of sampling: *1* for first sample taken, and *2* for the second sample per subject. Two nasal specimens will be collected from each subject. The SAD devices, however, will be randomized to the method of analysis (SA Device and SA Quantitative Analysis versus SA Semi-Quantitative Analysis), using a blinded randomization scheme prior to transport to the clinical lab.
The samples will be transported to the microbiology laboratory utilized by the site. At the end of the study, leftover eluates, swabs and cartridges will be frozen, stored and shipped to the sponsor for testing at a later date as needed and ultimately destroyed.

Study Duration:
One visit is required per subject for study enrollment and nasal sampling during preoperative visit. It is expected that this visit will be less than one hour. The study is to be completed in approximately 16 weeks.

Study burden and risks

There are no anticipated or known health risks associated with participation in this study. The dry rayon fiber bud of the SAD is the only swabbing component that will make contact with the human nasal mucosa. The swab buds are commercially available fiber materials. The incidence and severity of irritation is expected to be low or not detectable.

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

Subjects who are ambulatory (able to walk unaided or with a cane, walker, wheelchair) on the day of their pre-operative visit for their non emergeny surgery.

Exclusion criteria

Subjects who are on the nasal topical antibiotic Mupirocin (Bactroban® Nasal Ointment) within the last 4 weeks.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2006
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

Date:	30-11-2006
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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
CCMO	NL14036.101.06